AOAC INTERNATIONAL

The Scientific Association Dedicated to Analytical Excellence®

THE ELEVENTH MEETING

of the

AOAC Stakeholder Panel on Infant Formula and Adult Nutritionals

Meeting held at:
Hilton Washington DC North/Gaithersburg
620 Perry Parkway
Gaithersburg, MD 20877

Tuesday, March 17, 2015

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AOAC INTERNATIONAL
BYLAWS

As Amended September 26, 2010

ARTICLE I
Name

The name by which this Association shall be known is "AOAC INTERNATIONAL" (hereinafter referred to as the "Association").[1]

ARTICLE II
Purpose

The primary purpose of the Association is to promote methods validation and quality measurements in the analytical sciences.

ARTICLE III
Membership

Section 1. Types of Membership

There shall be three (3) types of membership in the Association: Individual Members, Sustaining Member Organizations, and Organizational Affiliates.

A. Individual Members

There shall be four (4) categories of Individual Members in the Association: Members, Retired Members, Student Members, and Honorary Members.

B. Sustaining Member Organizations

There shall be one (1) category of Sustaining Member Organizations.

C. Organizational Affiliate

There shall be one (1) category of Organizational Affiliate.

Section 2. Qualifications for Membership

A. Individual Members

[1] Members

Qualifications for Members shall be a degree in science, or equivalent as approved by the Board of Directors, and interest in supporting and furthering the purpose and goals of the Association. Such scientists shall be eligible for membership provided they are engaged, or have been engaged, directly or indirectly, in a field relevant to the purpose of the Association.

[2] Retired Members

[1] AOAC INTERNATIONAL was incorporated in the District of Columbia on January 20, 1932, as the Association of Official Agricultural Chemists. On November 10, 1965, the name of the corporation was changed to the Association of Official Analytical Chemists, and on September 12, 1991, the current name was adopted.

A current Member who is no longer actively engaged, directly or indirectly, in a field relevant to the purpose of the Association but who has served the Association as a Member for at least ten (10) years shall be eligible for Retired Member status upon written request and payment of the annual Retired Member dues. Any special benefits accorded Retired Members shall be determined by the Executive Director.

[3] Student Members

Any full-time student working toward an undergraduate or graduate degree in the areas of chemistry, microbiology, food science or other related science shall be eligible for Student Membership in AOAC INTERNATIONAL.

[4] Honorary Members

Honorary Members shall be persons recognized for their substantial contribution toward the achievement of the objectives of the Association. They shall be nominated by the Board of Directors and may be elected by a two-thirds vote of the Individual Members voting.

B. Sustaining Member Organizations

A Sustaining Member Organization shall be any agency of a local, state, provincial, national, or international government; a university, college, or academic department; or any firm, business, or organization with an interest in supporting and furthering the purpose of the Association. Every Sustaining Member Organization must have a designated representative(s). All such Sustaining Member Organization representatives must meet the qualifications for Members and become Individual Members with all the rights and privileges thereof.

C. Organizational Affiliate

An Organizational Affiliate Organization shall be any agency of a local, state, provincial, national, or international government; a university, college, or academic department; or any firm, business, or organization with an interest in supporting and furthering the purpose of the Association. Every Organizational Affiliate must have a designated representative(s). All such Organizational Affiliate representatives must meet the qualifications for Members and become Individual Members with all the rights and privileges thereof.

Section 3. Application for Membership

Applications or requests for membership shall be submitted to the Association's headquarters office. Membership shall become effective upon approval of the application or request, payment of any required membership dues, entry on the membership rolls, and assignment of a member number.

Section 4. Expulsion

The Board of Directors, at any duly called meeting of the Board, by a two-thirds vote of those holding office, may terminate the membership of any member who in its judgment has violated the Bylaws or has been guilty of conduct detrimental to the best interests of the Association. Any member convicted of a felony is subject to immediate expulsion from the Association. Expulsion of a member by the Board of Directors shall be final and shall cancel all rights, interest, or privileges of such member in the services or resources of the Association. Any member, for whom expulsion is proposed, for reasons other than conviction of a felony, shall be entitled to not less than 60 days advance notice of the charges, the date upon which a hearing will be scheduled, and the right to present evidence in defense. The date and place of any such hearing, if held other than at the headquarters or annual meeting site of the Association, must be reasonable with respect to the location of any individual so charged.

Section 5. Dues, Membership Year, and Waivers

A. Annual dues for membership in the Association shall be fixed by the Board of Directors, subject to approval by the majority of the Individual Members voting by ballot by any of the following means (whichever is deemed appropriate by the Board at the time): mail, telephone call, telegram, cablegram, electronic mail or other means of electronic or telephonic transmission.

B. Honorary Members of the Association shall be exempt from payment of dues and annual meeting registration fees.

C. The membership year and the delinquency date shall be determined by the Board of Directors.

D. The authority to grant waivers of membership dues rests with Executive Director.

E. Student Member dues shall be one-third of regular Member dues, rounded up to the nearest $5.00 increment.

Section 6. Members in Good Standing; Rights and Privileges

All Individual Members who maintain their membership by payment of dues as required under these Bylaws and who otherwise qualify shall be considered in good standing and entitled to full privileges of membership.

ARTICLE IV
Officers

Section 1. Elected Officers

The elected officers of the Association shall be Individual Members and shall consist of a President, President-Elect, Secretary, Treasurer, and Immediate Past President.

A. President

The President shall be the principal elected officer of the Association, shall preside at meetings of the Association and of the Board of Directors and of the Executive Committee, and shall be a member ex-officio, with right to vote, of all committees except the Nominating Committee. He or she shall also, at the annual meeting of the Association and at such other times as he or she shall deem proper, communicate to the Association or the Board of Directors such matters and make such suggestions as may in his or her opinion tend to promote the welfare and further the purpose of the Association and shall perform such other

duties as are necessarily incident to the office of President or as may be prescribed by the Board of Directors.

B. President-Elect

In the absence of the President, or in the event of the President's inability or refusal to act, the President-Elect shall perform the duties of the President, and, when so acting, shall have all the powers of and be subject to all the restrictions upon the President. The President-Elect shall perform such other duties as from time to time may be assigned to him or her by the President or by the Board of Directors.

C. Secretary

The Secretary shall give notice of all meetings of the Association, keep a record of all proceedings, attest documents, and, in general, perform such other duties as are usual of the office of Secretary and such other duties as may be assigned by the President or by the Board of Directors.

D. Treasurer

The Treasurer shall be responsible for the funds and securities of the Association; serve as financial officer of the organization and as Chairperson of the Finance Committee; manage the Board of Director's review of and action related to the Board of Director's financial responsibilities; serve as the chief Board liaison in overseeing and reviewing the annual audit, and in general, perform such other duties as are usual of the office of Treasurer and such other duties as may be assigned by the President or by the Board of Directors.

E. Immediate Past President

The Immediate Past President shall serve as advisor to the President and Directors and perform such other duties as may be assigned from time to time by the President or by the Board of Directors.

Section 2. Appointed Officers

The appointed officers shall include the Executive Director and such other appointed officers as may be designated by the Board of Directors from time to time.

A. Executive Director

The day-to-day administration and management of the Association's offices shall be vested in a salaried manager employed or appointed by, and directly responsible to, the Board of Directors. This manager shall have the title of Executive Director with responsibility for the management and direction of all operations, programs, activities, and affairs of the Association, as approved or delegated by the Board of Directors. The Executive Director shall have direct responsibility for employment and termination of employment and the determination of compensation for staff members within the budgetary framework determined by the Board of Directors. The Executive Director functions as the chief operating officer of the Association within the guidelines established by the policies and procedures of the Board of Directors and, as necessary, with the concurrence of the President. The Executive Director shall have such other duties as may be prescribed by the Board.

B. Other Appointed Officers

Other appointed officers shall have such duties as may be prescribed by the Board.

ARTICLE V
Nominations, Elections, Terms, and Appointments to the Board of Directors

Section 1. Nominating Committee

The Nominating Committee shall annually recommend to the Board of Directors a slate of Individual Members as potential nominees for the elected positions where vacancies will occur. The Nominating Committee shall consist of five (5) members who shall be three (3) immediate Past Presidents, as available, and two (2) Individual Members-at-Large of the Association. If three Past Presidents are not available to serve, other Individual Members-at-Large shall be appointed by the President to the extent necessary to form the five (5)-member committee.

Section 2. Elections and Terms of Office

The President-Elect, the Secretary, Treasurer, and the Directors of the Board of Directors shall be elected by a majority of Individual Members voting, from a slate of nominees recommended annually by the Board of Directors.

Terms of office for all Officers and Directors shall begin with the adjournment of the annual meeting following their election and shall end with the adjournment of the annual meeting occurring nearest the expiration of their term. The six (6) Directors shall be elected to staggered three-year terms with two Directors elected to full three-year terms each year, but not to more than two (2), consecutive, three-year terms. Appointment or election to fill an unexpired term shall not affect the eligibility of a person to subsequently be elected to two (2) full terms. The Secretary shall be elected to a one-year term and may be re-elected to successive one-year terms. The Treasurer shall be elected for a one-year term and may be re-elected to successive one-year terms. The President-Elect shall be elected to a one-year term; whereupon the current President-Elect shall become President and the current President shall become the Immediate Past President, each serving a one-year term.

Section 3. Appointments

Directors-at-Large are appointed by the Board in accordance with Article VI, Section 2. Directors-at-Large are appointed for one (1) year terms, renewable at the discretion of the elected Board.

ARTICLE VI
Board of Directors

Section 1. Composition

The Board of Directors shall consist of eleven (11) elected members to include the President, President-Elect, Secretary, Treasurer, Immediate Past President, six (6) Directors, and up to three (3) appointed Directors-at-Large, all of whom shall be Individual Members of the Association. The elected Board shall reflect the makeup of the Association membership and shall not be dominated by any single interest.

Section 2. Powers and Duties

The Board of Directors shall provide supervision, control, and direction of the affairs of the Association, shall determine the Association's policies or changes therein within the limits of the Bylaws, shall actively prosecute

its purpose, and shall have discretion in the disbursement of its funds. It may adopt such rules and procedures for the conduct of its business as shall be deemed advisable, and may, in the execution of the powers granted, appoint such agents as it may consider necessary. The Board of Directors may appoint up to three (3) Directors-at-Large, if, in their opinion, such appointments advance the purpose of the Association. Directors-at-Large shall be accorded the same voting privileges as elected Directors.

Section 3. Meetings

Except that the Board shall have a regular meeting at the time and place of the annual meeting, the Board shall meet, in person or via telephone conference call, upon call of the President at such times and places as he or she may designate within the policies adopted by the Board, and shall be called to meet upon demand of a majority of its members. Notice of all meetings of the Board of Directors shall be sent by any of the following means (whichever is deemed appropriate by the President at the time): mail, telephone call, telegram, cablegram, electronic mail or other means of electronic or telephonic transmission to each member of the Board at his or her last recorded address or number at least fourteen (14) days in advance of in-person meetings or forty-eight (48) hours in advance of conference call meetings.

Section 4. Quorum

A quorum for any meeting of the Board is six (6) Board members elected in accordance with Article V (1). Any less number may: (1) set a time to adjourn, (2) adjourn, (3) recess, or (4) take measures to obtain a quorum.

Section 5. Absence

Any member of the Board of Directors unable to attend a meeting of the Board shall notify the President and state the reason for his or her absence. If a member of the Board is absent from two (2) consecutive meetings, he or she may be removed by a two-thirds vote of the Board Members then in office.

Section 6. Compensation

Members of the Board of Directors, as such, shall not receive any compensation for their services as Board members, but the Board may, by resolution under policies it may adopt, authorize reimbursement of expenses incurred in the performance of members' duties. Such authorization may prescribe conditions and procedures for approval and payment of such expenses. Nothing herein shall preclude a Board member from serving the Association in any other capacity and receiving compensation for such services, if compensation is customarily paid for such services.

Section 7. Resignation or Removal

Any member of the Board may resign at any time by giving written notice to the President, Secretary, Treasurer, or to the Board of Directors. Such resignation shall take effect at the time specified therein, or, if no time is specified, at the time of acceptance thereof as determined by the President or the Board.

Any member of the Board may be removed by a three-fourths vote of the Board members then in office and present at any regular or special meeting of the Board.

Section 8. Vacancies: Members of the Board

If a vacancy should occur in the membership of the elected Board of Directors, any Past President may be appointed by action of the remaining members of the Board to temporarily fill such vacancy until the next

regularly scheduled election. At the next regularly scheduled election nominations will be presented to fill the vacancy for the unexpired portion of the term remaining.

Section 9. Vacancies: President and Other Officers

If the office of the President shall become vacant, the President-Elect shall thereupon become President of the Association for the unexpired term, followed by his or her duly elected term. In the event the office of President becomes vacant at a time when the office of President-Elect is also vacant, the Presidency shall be filled for the remainder of the term by the action of the Board of Directors. If any other officer position shall become vacant, the office may be filled for the remainder of the term by action of the Board.

ARTICLE VII
Committees

Section 1. Committee Formation

The Board of Directors shall form and adopt terms of reference for such standing or special boards, committees, subcommittees, task forces, or task groups as may be required by these Bylaws or as the Board may determine necessary to carry out the affairs of the Association.

Section 2. Committee Appointments

Subject to the requirements of these Bylaws and the specific terms of reference adopted by the Board, the President shall make the appointments to fill the vacancies occurring in the Association's standing or special boards, committees, subcommittees, task forces, or task groups.

ARTICLE VIII
Official Methods of Analysis

The Board of Directors (BoD) is empowered to develop written policies and procedures for the study, adoption, and change in status of the Official Methods of Analysis of AOAC INTERNATIONAL. Implementation of the policies and procedures shall be delegated to an Official Methods Board (OMB).

Section 1. Composition of the Official Methods Board

The Official Methods Board shall consist of a chair and a vice chair, and members who are recommended by the chair. The chair, vice chair and members are appointed by the President of AOAC INTERNATIONAL. The OMB shall be composed of members representing a balance of government, industry, and academia as appropriate to the scope of the group and shall not be dominated by any single interest.

Section 2. Purpose of the Official Methods Board

The OMB shall serve the Association in a scientific and advisory capacity on methods and the process of their adoption. The OMB shall be responsible for implementation of procedures adopted by the BoD, according to the principles in section 3 below.

Section 3. Principles of the Official Methods Program

A. Adequate records of technical data, discussions, and decisions on the study, adoption, and change of status of Official Methods of Analysis shall be maintained for a reasonable time.

B. Timely notice of proposed method studies, adoption, or change in status shall be published in an Association publication that is circulated to the members.

C. Opportunity shall be provided for materially interested parties to submit input during method study and adoption procedures and to submit comments on the adoption, use of, or change in status of specific methods.

D. Methods submitted to the OMB for inclusion in the OMA shall be thoroughly studied, scientifically reviewed, and available in published form prior to adoption as Final Action by the OMB.

E. The OMB shall adopt methods as Final Action.

ARTICLE IX
Meetings

Section 1. Annual Meeting

The annual business meeting of the Association shall be held at the time and place decided by the Board of Directors. A special meeting of the entire Association may be called by the Board of Directors; announcement thereof shall be made at least thirty (30) days prior to the time of said meeting.

Section 2. Quorum

One hundred Individual Members who are present in person or by proxy and entitled to vote shall constitute a quorum at any meeting of the Association which is duly called pursuant to the provisions of these Bylaws.

ARTICLE X
Voting

Section 1. Voting by Ballot

By direction of the Board of Directors, unless otherwise required by these Bylaws or conducted under alternative procedures established under these Bylaws, voting on any matter, including the election of officers and directors, the election of Honorary Members, amendment of the Bylaws, and the approval of dues, may be conducted by ballot of the voting membership by any of the following means (whichever is deemed appropriate at the time): mail, telephone call, telegram, cablegram, electronic mail or other means of electronic or telephonic transmission, and the question(s) thus presented shall be determined according to the votes received, provided in each case votes of at least five (5) percent of the voting membership shall be received. Any and all action taken in pursuance of a vote by any of the means indicated above (whichever the Board deemed appropriate at the time)

in each case shall be binding upon the Association in the same manner as would be action taken at a duly called meeting and shall become effective, unless otherwise provided for in these Bylaws or otherwise stated in the ballot, on the day following certification of the vote.

Section 2. Voting by Proxy

At any duly called meeting of Individual Members, a member-of-record, as determined thirty (30) days prior to any meeting and who is entitled to vote, may vote by proxy executed in writing by the Individual Member or his or her duly authorized attorney-in-fact. No proxy shall be valid for more than eleven (11) months after the date of its execution unless otherwise provided in the proxy.

ARTICLE XI
Earnings and Assets

Section 1. Non-Profit Status

A. Regardless of any provision of the Bylaws which may be construed otherwise:

[1] No part of the net earnings of the Association shall under any circumstances inure to the benefit of any member or individual.

[2] The Association shall not be operated for a private profit.

B. On lawful dissolution of the Association and after settlement of all just obligations of the Association, the Board of Directors shall distribute all remaining assets of the Association to one (1) or more organizations selected by the Board of Directors which have been held exempt from Federal Income Tax as organizations described in section 501(c)(3) of the Internal Revenue Code of 1954.

Section 2. Political Activities

A. No substantial part of the Association's activities shall consist of carrying on propaganda or otherwise attempting to influence local, state, or national legislation. All activities of the Association shall be determined by the Board of Directors.

B. The Association shall not participate or intervene in any manner in any campaign on behalf of any candidate for a political office.

ARTICLE XII
Sections

Section 1. Sections

The Board of Directors shall set geographic limits and grant authority to groups of Individual Members of the Association residing or working in the same geographical areas for the establishment of Sections.

Section 2. Purpose of Sections

The purpose of Sections shall be to promote and further the purpose of the Association.

Section 3. Membership in Sections

Individuals interested in the purpose of the Section shall be eligible for Section membership. Only Individual Members of the Association shall be eligible for election to the Executive Committee of the Section.

Section 4. Bylaws of Sections

Subject to approval of the Board of Directors, each Section shall adopt, for its own governance, bylaws not inconsistent with these Bylaws.

Section 5. Dissolution of Sections

When any Section shall cease to function as a Section for a period of more than one year, or if its membership shall be less than ten (10) Individual Members of the Association for a period of one (1) year, the Board of Directors may terminate the existence of such Section.

Section 6. Actions of Sections

No act of a Section or its members shall be considered an act of the Association unless expressly authorized, ratified, or affirmed by the Board of Directors.

ARTICLE XIII
Technical Divisions

Section 1. Purpose

Technical Divisions shall represent communities of interest within the Association which have the purpose of furthering the purpose of the Association through the development of the analytical sciences either in a commodity-based or scientific discipline-based field. Their activities shall not duplicate the organizational structure nor conflict with the policies or procedures for the adoption of official methods of analysis by the Association.

Section 2. Creation, Combination, Discontinuance, or Change

Technical Divisions may be created, existing Technical Divisions may be combined or discontinued, or the name of a Technical Division may be changed under policies and procedures adopted by the Board of Directors. Each Technical Division shall adopt bylaws not inconsistent with these Bylaws. The jurisdiction of each Technical Division shall be described in its bylaws. No act of any Technical Division or its members shall be considered an act of the Association unless expressly authorized, ratified, or affirmed by the Board of Directors.

ARTICLE XIV
Indemnification

The Association shall have the power to pay, by indemnity, reimbursement, or otherwise, to or for the use of any person designated by resolution of the Board of Directors who was or is a party or is threatened to be made a party to any threatened, pending, or completed action, suit, or proceeding, whether civil, criminal, administrative, or investigative (other than an action by or on behalf of the Association), by reason of the fact he or she is or was a director, officer, committee member, employee or agent of the Association, or was serving as such for another at the request of the Association, against expenses (including legal, accounting, witness and other), judgments, fines, and amounts paid in settlement so long as such person was not found by a court of competent jurisdiction to have been willfully negligent of the interests of the Association or such person had reasonable cause to believe that his or her conduct was lawful.

ARTICLE XV
Parliamentary Authority

The rules contained in the current edition of *Robert's Rules of Order Newly Revised* shall govern the Association in all cases in which they are applicable and in which they are not inconsistent with these Bylaws or any special rules of order the Association may adopt.

ARTICLE XVI
Amendments to the Bylaws

These Bylaws may be amended, repealed, or altered, in whole or in part, by a three-fourths vote: (a) of the Individual Members at any annual business or duly called special meeting of the Association, provided notice of any amendment proposed for consideration shall be sent by any of the following means (whichever may be deemed appropriate at the time): mail, telephone call, telegram, cablegram, electronic mail or other means of electronic or telephonic transmission to the last recorded address or number of each Individual Member at least thirty (30) days prior to the date of the meeting; or (b) by approval of the Individual Members through ballot sent by any means indicated above in accordance with the provisions of Article X, Voting.

All proposed amendments of these Bylaws shall be presented in writing to the Board of Directors. The Board shall present the proposals to the Association membership, with recommendations. All amendments to the Bylaws, unless otherwise stated, will become effective at the adjournment of the meeting where action is taken or on the day following the certification of a vote by mail ballot.

AOAC INTERNATIONAL
POLICY ON THE USE OF THE
ASSOCIATION NAME, INITIALS,
IDENTIFYING INSIGNIA, LETTERHEAD, AND BUSINESS CARDS

Introduction

The following policy and guidelines for the use of the name, initials, and other identifying insignia of AOAC INTERNATIONAL have been developed in order to protect the reputation, image, legal integrity and property of the Association.

The name of the Association, as stated in its bylaws, is "AOAC INTERNATIONAL". The Association is also known by its initials, AOAC, and by its logo, illustrated below, which incorporates the Association name and a representation of a microscope, book, and flask. The AOAC logo is owned by the Association and is registered with the U.S. Patent and Trademark Office.

The full Association insignia, illustrated below, is comprised of the logo and the tagline, "The Scientific Association Dedicated to Analytical Excellence," shown below. The typeface used is Largo. The AOAC tagline is owned by the Association and is registered with the U.S. Patent and Trademark office.

The Scientific Association Dedicated to Analytical Excellence®

Policy

Policy on the use of the Association's name and logo is established by the AOAC Board of Directors as follows:

> "The Board approves and encourages reference to the Association by name, either as AOAC INTERNATIONAL or as AOAC; or reference to our registered trademark, AOAC®, in appropriate settings to describe our programs, products, etc., in scientific literature and other instances so long as the reference is fair, accurate, complete and truthful and does not indicate or imply unauthorized endorsement of any kind.
>
> The insignia (logo) of AOAC INTERNATIONAL is a registered trade and service mark and shall not be reproduced or used by any person or organization other than the Association, its elected and appointed officers, sections, or committees, without the prior written permission of the Association. Those authorized to use the AOAC INTERNATIONAL insignia shall use it only for the purposes for which permission has been specifically granted.
>
> The name and insignia of the Association shall not be used by any person or organization in any way which indicates, tends to indicate, or implies AOAC official endorsement of any product, service, program, company, organization, event or person, endorsement of which, has not been authorized by the Association, or which suggests that membership in the Association is available to any organization."

The Executive Director, in accordance with the above stated policy, is authorized to process, approve, fix rules, and make available materials containing the Association name and insignia.

It should be noted that neither the Association's name nor its insignia nor part of its insignia may be incorporated into any personal, company, organization, or any other stationery other than that of the Association; nor may any statement be included in the printed portion of such stationery which states or implies that an individual, company, or other organization is a Member of the Association.

Instructions

1. Reproduction or use of the Association name or insignia requires prior approval by the Executive Director or his designate.

2. Association insignia should not be altered in any manner without approval of the Executive Director or his designate, except to be enlarged or reduced in their entirety.

3. Artwork for reproducing the Association name or insignia, including those incorporating approved alterations, will be provided on request to those authorized to use them (make such requests to the AOAC Marketing Department). Examples of the types of alterations that would be approved are inclusion of a section name in or the addition of an officer's name and address to the letterhead insignia.

4. When the Association name is used without other text as a heading, it should, when possible, be set in the Largo typeface.

5. Although other colors may be used, AOAC blue, PMS 287, is the preferred color when printing the AOAC insignia, especially in formal and official documents. It is, of course, often necessary and acceptable to reproduce the insignia in black.

6. Do not print one part of the logo or insignia in one color and other parts in another color.

7. The letterhead of AOAC INTERNATIONAL shall not be used by any person or organization other than the Association, its elected and appointed officers, staff, sections, or committees; except by special permission.

   Correspondence of AOAC official business should be conducted using AOAC letterhead. However, those authorized to use AOAC letterhead shall use it for official AOAC business only.

   Copies of all correspondence using AOAC letterhead or conducting AOAC official business, whether on AOAC letterhead or not, must be sent to the appropriate office at AOAC headquarters.

8. AOAC INTERNATIONAL business cards shall not be used by any person or organization other than the Association, its staff, and elected officials, except by special permission.

   Those authorized to use AOAC business cards shall use them for official AOAC business only and shall not represent themselves as having authority to bind the Association beyond that authorized.

Sanctions

1. Upon learning of any violation of the above policy, the Executive Director or a designate will notify the individual or organization that they are in violation of AOAC policy and will ask them to refrain from further misuse of the AOAC name or insignia.

2. If the misuse is by an Individual Member or Sustaining Member of the Association, and the misuse continues after notification, the Board of Directors will take appropriate action.

3. If continued misuse is by a nonmember of the Association or if a member continues misuse in spite of notification and Board action, ultimately, the Association will take legal action to protect its property, legal integrity, reputation, and image.

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Adopted by the AOAC Board of Directors: September 24, 1989
Revised: June 13, 1991; February 26, 1992; March 21, 1995; October 1996

AOAC INTERNATIONAL
ANTITRUST POLICY
STATEMENT AND GUIDELINES

Introduction

It is the policy of AOAC INTERNATIONAL (AOAC) and its members to comply strictly with all laws applicable to AOAC activities. Because AOAC activities frequently involve cooperative undertakings and meetings where competitors may be present, it is important to emphasize the on_going commitment of our members and the Association to full compliance with national and other antitrust laws. This statement is a reminder of that commitment and should be used as a general guide for AOAC and related individual activities and meetings.

Responsibility for Antitrust Compliance

The Association's structure is fashioned and its programs are carried out in conformance with antitrust standards. However, an equal responsibility for antitrust compliance __ which includes avoidance of even an appearance of improper activity __ belongs to the individual. Even the appearance of improper activity must be avoided because the courts have taken the position that actual proof of misconduct is not required under the law. All that is required is whether misconduct can be inferred from the individual's activities.

Employers and AOAC depend on individual good judgment to avoid all discussions and activities which may involve improper subject matter and improper procedures. AOAC staff members work conscientiously to avoid subject matter or discussion which may have unintended implications, and counsel for the Association can provide guidance with regard to these matters. It is important for the individual to realize, however, that the competitive significance of a particular conduct or communication probably is evident only to the individual who is directly involved in such matters.

Antitrust Guidelines

In general, the U.S. antitrust laws seek to preserve a free, competitive economy and trade in the United States and in commerce with foreign countries. Laws in other countries have similar objectives. Competitors (including individuals) may not restrain competition among themselves with reference to the price, quality, or distribution of their products, and they may not act in concert to restrict the competitive capabilities or opportunities of competitors, suppliers, or customers.

Although the Justice Department and Federal Trade Commission generally enforce the U.S. antitrust laws, private parties can bring their own lawsuits.

Penalties for violating the U.S. and other antitrust laws are severe: corporations are subject to heavy fines and injunctive decrees, and may have to pay substantial damage judgments to injured competitors, suppliers, or customers. Individuals are subject to criminal prosecution, and will be punished by fines and imprisonment.
Under current U.S. federal sentencing guidelines, individuals found guilty of bid rigging, price fixing, or market allocation must be sent to jail for at least 4 to 10 months and must pay substantial minimum fines.

Since the individual has an important responsibility in ensuring antitrust compliance in AOAC activities, everyone should read and heed the following guidelines.

1. Don't make any effort to bring about or prevent the standardization of any method or product for the purpose or intent of preventing the manufacture or sale of any method or product not conforming to a specified standard.

2. Don't discuss with competitors your own or the competitors' prices, or anything that might affect prices such as costs, discounts, terms of sale, distribution, volume of production, profit margins, territories, or customers.

3. Don't make announcements or statements at AOAC functions, outside leased exhibit space, about your own prices or those of competitors.

4. Don't disclose to others at meetings or otherwise any competitively sensitive information.

5. Don't attempt to use the Association to restrict the economic activities of any firm or any individual.

6. Don't stay at a meeting where any such price or anti_competitive talk occurs.

7. Do conduct all AOAC business meetings in accordance with AOAC rules. These rules require that an AOAC staff member be present or available, the meeting be conducted by a knowledgeable chair, the agenda be followed, and minutes be kept.

8. Do confer with counsel before raising any topic or making any statement with competitive ramifications.

9. Do send copies of meeting minutes and all AOAC_related correspondence to the staff member involved in the activity.

10. Do alert the AOAC staff to any inaccuracies in proposed or existing methods and statements issued, or to be issued, by AOAC and to any conduct not in conformance with these guidelines.

Conclusion

Compliance with these guidelines involves not only avoidance of antitrust violations, but avoidance of any behavior which might be so construed. Bear in mind, however, that the above antitrust laws are stated in general terms, and that this statement is not a summary of applicable laws. It is intended only to highlight and emphasize the principal antitrust standards which are relevant to AOAC programs. You must, therefore, seek the guidance of either AOAC counsel or your own counsel if antitrust questions arise.

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Adopted by the AOAC Board of Directors: September 24, 1989
Revised: March 11, 1991
Revised October 1996

AOAC INTERNATIONAL

POLICY AND PROCEDURES ON

VOLUNTEER CONFLICT OF INTEREST

Statement of Policy

While it is not the intention of AOAC INTERNATIONAL (AOAC) to restrict the personal, professional, or proprietary activities of AOAC members nor to preclude or restrict participation in Association affairs solely by reason of such activities, it is the sense of AOAC that conflicts of interest or even the appearance of conflicts of interest on the part of AOAC volunteers should be avoided. Where this is not possible or practical under the circumstances, there shall be written disclosure by the volunteers of actual or potential conflicts of interest in order to ensure the credibility and integrity of AOAC. Such written disclosure shall be made to any individual or group within the Association which is reviewing a recommendation which the volunteer had a part in formulating and in which the volunteer has a material interest causing an actual or potential conflict of interest.

AOAC requires disclosure of actual or potential conflicts of interest as a condition of active participation in the business of the Association. The burden of disclosure of conflicts of interest or the appearance of conflicts of interest falls upon the volunteer.

A disclosed conflict of interest will not in itself bar an AOAC member from participation in Association activities, but a three-fourths majority of the AOAC group reviewing the issue presenting the conflict must concur by secret ballot that the volunteer's continued participation is necessary and will not unreasonably jeopardize the integrity of the decision-making process.

Employees of AOAC are governed by the provision of the AOAC policy on conflict of interest by staff. If that policy is in disagreement with or mute on matters covered by this policy, the provisions of this policy shall prevail and apply to staff as well.

Illustrations of Conflicts of Interest

1. A volunteer who is serving as a committee member or referee engaged in the evaluation of a method or device; who is also an employee of or receiving a fee from the firm which is manufacturing or distributing the method or device or is an employee of or receiving a fee from a competing firm.

2. A volunteer who is requested to evaluate a proposed method or a related collaborative study in which data are presented that appear detrimental (or favorable) to a product distributed or a position supported by the volunteer's employer.

3. A referee who is conducting a study and evaluating the results of an instrument, a kit, or a piece of equipment which will be provided gratis by the manufacturer or distributor to one or more of the participating laboratories, including his or her own laboratory, at the conclusion of the study.

4. Sponsorship of a collaborative study by an interest (which may include the referee) which stands to profit from the results; such sponsorship usually involving the privilege granted by the investigator to permit the sponsor to review and comment upon the results prior to AOAC evaluation.

5. A volunteer asked to review a manuscript submitted for publication when the manuscript contains information which is critical of a proprietary or other interest of the reviewer.

The foregoing are intended as illustrative and should not be interpreted to be all-inclusive examples of conflicts of interest AOAC volunteers may find themselves involved in.

Do's and Don'ts

Do avoid the appearance as well as the fact of a conflict of interest.

Do make written disclosure of any material interest which may constitute a conflict of interest or the appearance of a conflict of interest.

Do not accept payment or gifts for services rendered as a volunteer of the Association without disclosing such payment or gifts.

Do not vote on any issue before an AOAC decision-making body where you have the appearance of or an actual conflict of interest regarding the recommendation or decision before that body.

Do not participate in an AOAC decision-making body without written disclosure of actual or potential conflicts of interest in the issues before that body.

Do not accept a position of responsibility as an AOAC volunteer, without disclosure, where the discharge of the accepted responsibility will be or may appear to be influenced by proprietary or other conflicting interests.

Procedures

Each volunteer elected or appointed to an AOAC position of responsibility shall be sent, at the time of election or appointment, a copy of this policy and shall be advised of the requirement to adhere to the provisions herein as a condition for active participation in the business of the Association. Each volunteer, at the time of his or her election or appointment, shall indicate, in writing, on a form provided for this purpose by AOAC, that he or she has read and accepts this policy.

Each year, at the spring meeting of the AOAC Board of Directors, the Executive Director shall submit a report certifying the requirements of this policy have been met; including the names and positions of any elected or appointed volunteers who have not at that time indicated in writing that they have accepted the policy.

Anyone with knowledge of specific instances in which the provisions of this policy have not been complied with shall report these instances to the Board of Directors, via the Office of the Executive Director, as soon as discovered.

* * * * * *

Adopted: March 2, 1989
Revised: March 28, 1990
Revised: October 1996

AOAC INTERNATIONAL

Stakeholder Panel for Infant Formula and Adult Nutritionals (SPIFAN)

Meeting at Hilton Washington DC North/Gaithersburg

620 Perry Parkway, Gaithersburg, MD 20877

STAKEHOLDER PANEL - DRAFT MEETING AGENDA

Tuesday, March 17, 2015

Meeting Start Time: 8:30AM (Eastern US)

SPIFAN Chair: Darryl Sullivan

(Covance Laboratories)

Location: Salon A/B

Registration Opens at 7:30AM

I. INTRODUCTION (Bradford/Sullivan-8:30AM-8:40AM)

Jim Bradford (AOAC)/Darryl Sullivan (Covance) will call the Stakeholder Panel meeting to order along with the introduction/welcome of participants, and review AOAC's Antitrust and Conflict of Interest Policies. Voting Members of the stakeholder panel will be introduced.

II. SPIFAN OVERVIEW (Sullivan-8:40AM-9:00AM)

Darryl Sullivan (Covance) will provide an overview of the accomplishments and achievements in SPIFAN.

III. WHEY PROTEIN: CASEIN RATIO UPDATE (Sullivan-9:00AM-9:10AM)

Darryl Sullivan (Covance) will provide an update on Whey Protein: Casein Ratio.

IV. STANDARDS DEVELOPMENT PROCESS OVERVIEW (McKenzie-9:10AM-9:40AM)

Deborah McKenzie (AOAC) will provide an overview of the standards development process.

V. WORKING GROUP CHAIR PRESENTATIONS AND VOTE ON FINAL SMPR DOCUMENTS (Working Group Chair-9:40AM-10:40AM)

Working Group Chair will review and reach consensus on SMPRs.

1. ***WORKING GROUP CHAIR, Louis Salvati (Abbott Nutrition)***
   **Working Group Chair SMPR Approval Presentations*

   a. **VITAMIN B_1 (Thiamine)**

   b. **VITAMIN B_2 (Riboflavin)**

   c. **VITAMIN B_3 (Niacin)**

   d. **VITAMIN B_6 (Pyridoxine)**

VI. BACKGROUND INFORMATION ON SODIUM FLUOROACETATE (COMPOUND 1080) (Reddy-10:40AM-11:00AM)

Background information on the emerging issue surrounding the low level pesticide residue will be provided.

1. ***WORKING GROUP CHAIR, Joe Boison (CFIA)- 11:00AM-11:30AM***
   **Working Group Chair SMPR Approval Presentations*

   a. **LOW LEVEL PESTICIDE – SODIUM FLUOROACETATE (COMPOUND 1080)**

VII. INTRODUCTION OF PROPOSED INFANT FORMULA NUTRITIONAL INGREDIENTS PROGRAM (Sullivan-11:30AM-11:40AM)

Darryl Sullivan (Covance) will introduce the new AOAC SPIFAN Nutritional Ingredients program to define the safety and quality framework of nutritional ingredients for infant formula.

i. PROPOSED INFANT FORMULA NUTRITIONAL INGREDIENTS PROGRAM INCLUDING *Manufacturer's Perspective* (Reddy-11:40AM-12:00PM)

Murali Reddy (Abbott) will provide an overview and rationale of the new proposed AOAC SPIFAN Nutritional Ingredients program including global regulatory background information. Reddy will provide safety and quality framework of nutritional ingredients for infant formula. He will also provide the manufacturer's perspective in regards to dairy ingredients and contaminants.

ii. GLOBAL DAIRY SECTOR (Evers) – *IDF Perspective &* (deVreeze) *ISO/CEN Perspective*-12:00PM-12:40PM

Jaap Evers (IDF/ISO) will provide an organization's perspective in regards to dairy ingredients and contaminants and where there are gaps.

Marcel deVreeze will provide ISO/CEN's perspective with challenges in compositional and contaminants testing of dairy ingredients.

iii. CHALLENGES IN COMPOSITIONAL AND CONTAMINANTS TESTIING OF DAIRY INGREDIENTS (Cruijsen) – *Ingredient Companies Perspective*-12:40PM-1:10PM

Hans Cruijsen (FrieslandCampina) will provide the ingredient companies perspective in regards to dairy ingredients and contaminants.

iv. PRIORITY SESSION ON DAIRY INGREDIENTS (Stakeholders-1:10PM-2:00PM)

Stakeholders will establish criteria for prioritizing ingredients and identify top dairy ingredients and contaminants to launch in September 2015.

VIII. UPDATE ON AOAC/ISO ACTIVITIES (Bradford/Konings-2:00PM-2:20PM)

Jim Bradford (AOAC)/Erik Konings (Nestlé) will provide an update on AOAC/ISO cooperative.

IX. TIMELINES/DEADLINES/WRAP-UP (Sullivan/Mishra-2:20PM-2:30PM)

Darryl Sullivan (Covance) and Anita Mishra (AOAC) will provide a timeline of SPIFAN activities including upcoming deadlines, wrap up all discussions and answer any additional questions.

MEETING ITINERARY:

REGISTRATION (7:30AM)

MEETING START TIME (8:30AM)

MORNING BREAK (10:15AM-10:30AM)

LUNCH (12:00PM–1:00PM)

AOAC INTERNATIONAL
Stakeholder Panel Voting Members

AOAC INTERNATIONAL (AOAC) assembles stakeholder panels to develop voluntary consensus standards. While AOAC maintains transparency and openness in accordance with national and international guidance and regulations for standards development and its policies and procedures for assembling stakeholder panels, its policies and procedures also ensures that there is a balance of interests and perspectives in achieving consensus of the stakeholder panel.

Due Process and Balance

All AOAC stakeholder panels are diverse and can vary in size. Where a stakeholder panel is not balanced or if it is significantly large whereby consensus of the general assembly may be impractical, a balanced representative voting panel will be used to demonstrate consensus. AOAC encourages ALL stakeholders to participate in deliberations during stakeholder panel meetings and working group meetings, in addition to participating during any posted comment periods. To ensure that there is a balance of interests and perspectives, a ***representative subset*** of the stakeholder panel, the voting members, is selected to reach consensus for the development of AOAC voluntary consensus standards.

Composition

Voting members represent the perspectives of the larger stakeholder panel. The voting members consist of no more than ¼ to 1/3 of the total number of stakeholders in registered. Primary and secondary representative voting members are approved. Every attempt is made to approve a panel of voting members that represents all perspectives of the stakeholder panel. In the event of a primary voting member is not able to attend, and no alternate has been approved, the stakeholder panel chair, working with AOAC can provisionally approve an alternate from those in attendance to assure balance and lack of dominance. For stakeholder panels with scopes including diverse topics, the voting member representatives may be rotated to include other stakeholders for successive meetings to ensure a lack of dominance by any particular stakeholder.

Approval Process

AOAC works with the chair of the stakeholder panel and potentially other key stakeholders to develop a proposed representative voting member panel. Following AOAC policies and procedures, the proposed voting members and documentation are submitted to the AOAC Official Methods Board (OMB) for review and approval. The OMB's review ensures that the proposed panel is balanced in interests and perspectives representing the stakeholder panel and a lack of dominance.

Roles and Responsibilities

Every stakeholder has a voice and every stakeholder is entitled to state his/her or organizational perspective(s). This is due process. In developing AOAC standards, stakeholder consensus is demonstrated by 2/3 vote (67%) in favor of a motion to adopt a standard. It is important to note: Individual voting members do not have any additional weight, voice or status in stakeholder deliberations than other stakeholders. The role of the voting members is to demonstrate the consensus of the stakeholder panel. Voting members may vote in favor or against any motion and/or they may abstain. Stakeholder panel chair will moderate voting process. AOAC carefully documents the vote. It is important for voting members to be in the room during the time for voting. It is also important for voting members to inform the chair of his/her inability to serve as a voting member.

Definitions

Quorum — The number of members who must be present in order to validly transact business. It is determined by the number of members present, not the number present and voting. (Fundamentals of Parliamentary Law and Procedure, 3rd edition. p. 151).

Representative Voting Panel Members — Every member has an obligation to vote and the right to abstain.

Abstentions — Abstentions reduce the number required to obtain a majority of those present and voting. They are only counted to confirm the presence of a quorum. *(Fundamentals of Parliamentary Law and Procedure, 3rd edition. p. 237).*

Stakeholders Privileges

Order — Meetings should address only one item of business at one time (only one pending motion at a time). Chairs should not permit digression or introduction of different topics until the business at hand is resolved. No pending motions while changing topics. (*Fundamentals of Parliamentary Law and Procedure, 3rd edition. p. 1)*.

All business must be conducted with order and should be done fairly and impartially. The presiding officer should impartially ensure that each member has an opportunity to speak. *(Fundamentals of Parliamentary Law and Procedure, 3rd edition. pp. 1-2).*

Equality — All members have equal opportunity to propose motions, to participate in debate, to vote, to serve on committees or as an officer, to share in activities according to the member's abilities. *(Fundamentals of Parliamentary Law and Procedure, 3rd edition. p. 2).*

Justice — All members have the right to ask questions, to be informed, to have complex motions explained by the chair. *(Fundamentals of Parliamentary Law and Procedure, 3rd edition. p. 2).*

Minority Rights — Dissenting members have equal rights to voice opposing or minority opinions and strive to become the majority. *(Fundamentals of Parliamentary Law and Procedure, 3rd edition. p. 2).*

Majority Rights — No members, board, or officers have the right to dictate or control decisions unless the member grant such rights

Members may not take any action in conflict with federal, regional or organizational laws or policies.

Decisions are based on the will of the majority.
(Fundamentals of Parliamentary Law and Procedure, 3rd edition. p. 2).

STAKEHOLDER PANEL ON INFANT FORMULA AND ADULT NUTRITIONALS (SPIFAN)

Darryl Sullivan, SPIFAN Chair

Darryl Sullivan of Covance Laboratories is the Chairperson for the Stakeholder Panel on Infant Formula and Adult Nutritionals.

Appointed by President Gayle Lancette in July 2010, Darryl Sullivan has been a champion in previous AOAC stakeholder efforts on nutrients in infant formula and adult nutritionals. He is a Fellow of AOAC and has been an active member since 1980. He has served terms as secretary, president-elect, president, past president, and director of the Board of Directors, and previously served a three-year term as Chair of the Official Methods Board. Sullivan also served a three-year term as a director on the AOAC Research Institute Board of Directors. He was a founding member of the Presidential Task Force on Dietary Supplements and a member of the Task Force on *Bacillus anthracis*, as well as the AOAC Task Force on Nutrition Labeling and the AOAC Task Force on Sulfites. Prior to becoming Chair of the OMB, he served as a member and then Chair of the Methods Committee on Commodity Foods and Commodity Products. Darryl Sullivan has been involved with methods validation for over 25 years. In addition to being involved as a Study Director for several AOAC *Official Methods*^{SM}. Sullivan's expertise in methods validation is frequently called upon by AOAC and a number of other scientific associations. Sullivan was a founding member of the AOAC Technical Division on Reference Materials and served three terms on the Division's Executive Board. A staunch supporter of the Association, Sullivan was quite active in the e-CAM and Scholar I projects at AOAC, has exhibited at the annual meetings for many years, has presented hundreds of papers and posters at AOAC meetings, and regularly publishes his research in the journal of the AOAC. He has also presented a significant number of papers on behalf of AOAC at other scientific meetings.

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STAKEHOLDER PANEL ON INFANT FORMULA & ADULT NUTRITIONALS (SPIFAN)

SPIFAN OVERVIEW

Darryl Sullivan
AOAC INTERNATIONAL
March 17, 2015

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Outline

- AOAC SPIFAN Background and Overview
- AOAC SPIFAN Accomplishments
- AOAC SPIFAN Activities
- AOAC SPIFAN Expert Review Panel and Methods
- AOAC SPIFAN Activities during AOAC Mid-Year Meeting

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SPIFAN Overview

- Historical Perspective
  - AOAC infant formula methods were validated in 1980s
  - New formulas exposed some gaps in validated methods
  - Infant formula is highly regulated around the world
  - Regulatory agencies use AOAC methods

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AOAC Engages the Formula Industry

- Agreement with IFC signed in 2010
  - Identify gaps in methods used to analyze label nutrients in infant formula
  - Create AOAC voluntary consensus standards for methodology for 15 sets of nutrients
  - Evaluate and recommend "best" methods
  - AOAC established the Stakeholder Panel on Infant Formula and Adult Nutritionals (SPIFAN) to develop the voluntary consensus standards
- Second agreement with IFC signed in June 2013
  - Create standards for methodology for 9 sets of nutrients
- 7 stakeholder panel, WGs, and ERP meetings
  - 1/7 – AOAC Annual Meeting, Chicago - 2013
  - 2/7 – AOAC Mid-Year Meeting, Gaithersburg - 2014
  - 3/7 – AOAC Annual Meeting, Boca Raton – 2014
  - 4/7 – AOAC Mid-Year Meeting, Gaithersburg - 2015

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Voluntary Consensus Standards Development

SPIFAN I (SMPRs)
2011 – 2013

1. Vitamin A
2. Vitamin B12
3. Vitamin D
4. Folate
5. Inositol
6. Vitamin E
7. Whey Protein
8. Fatty Acids (ISO)
9. Carnitine
10. Vitamin C (India 2012)
11. Choline (India 2012)
12. Pantothenate
13. Iodine
14. Ultra Trace Minerals (Mo, Se, Cr)
15. Nucleotides

SPIFAN II (SMPRs)
2013 – 2016

March 2014 (launched 9/2013)

16. Vitamin K
17. FOS
18. GOS
19. Biotin
20. Minerals

September 2014 (launched 3/2014)

21. Amino Acids
22. Carotenoids
23. Fluoride
24. Chloride

March 2015 (launched 9/2014)

25. Vitamin B1 (thiamine)
26. Vitamin B2 (riboflavin)
27. Vitamin B3 (niacin)
28. Vitamin B6 (pyridoxine)

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SPIFAN II

- Signed June 13, 2013
- 7 stakeholder panel, WGs, and ERP meetings
  - 1/7 – AOAC Annual Meeting Chicago 2013
  - 2/7 – AOAC Mid-Year Meeting, Gaithersburg 2014
  - 3/7 – AOAC Annual Meeting, Boca Raton 2014
    - Launched: Vitamins B_1, B_2, B_3, and B_6
    - WGs drafted SMPRs for Vitamins B_1, B_2, B_3, and B_6
    - ERP evaluated methods for folate and choline/carnitine for First Action status.
    - ERP evaluated 7 First Action methods and recommended 6 to the AOAC Official Methods Board for Final Action status.

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Since the AOAC Annual Meeting

- SMPRs posted for Comments
  - Vitamin B_1, B_2, B_3, and B_6 WG chairs reviewed and reconciled comments
  - WG chairs reviewed and reconciled comments
- Call for Methods posted and/or submitted for ERP review
  - Minerals & Trace Elements Vitamin K, Biotin, FOS, and GOS
    - 3 Minerals & Trace Elements methods
    - 2 vitamin K methods
    - 3 biotin methods
    - 4 FOS methods
    - 2 GOS methods
  - Amino acids, Carotenoids, Fluoride, and Chloride
    - 1 Amino acids methods
    - 4 chloride methods
    - 2 fluoride methods
    - NO CAROTENOIDS METHODS SUBMITTED
  - Additional Submissions
    - 1 carnitine/choline method
    - 1 folate method
    - 4 First Action methods with reproducibility information and user feedback
- Call for Feedback on First Action Methods

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Since AOAC Annual Meeting

Industry Related Activities

- ISO Working Group meeting in Boca Raton followed the AOAC Annual Meeting in Sept. 2014
- APEC meeting planning in China followed AOAC Annual Meeting in Sept. 2014

AOAC SPIFAN Related Activities

- Looking into new initiative with infant formula ingredients
- CCMAS and Interagency Meetings in Budapest in February 2015

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Registered Organizations

- Abbott Laboratories / Abbott Nutrition
- American Dairy Products Institute
- Archer Daniels Midland Company
- AsureQuality, New Zealand
- Canadian Food Inspection Agency
- Covance Laboratories
- Eurofins
- Florida Department Of Agriculture and Consumer Services
- onterra Cooperative Group Ltd.
- Friesland Campina / Friesland Campina Domo
- Healthy Directions
- Hilmar Ingredients
- Infant Nutrition Council of America (INCA)
- Instituto Nacional de Tecnología Industrial
- International Dairy Foods Association
- Jamieson Laboratories
- Land O'Lakes/RTECH Analytical Laboratory
- LATU
- Leprino Foods
- Mead Johnson Nutrition
- Medallion Laboratories / General Mills
- National Milk Producers Federation
- Nestlé
- NIST
- NSF International
- Perrigo / PBM Nutritionals
- Phenomenex
- Premiumlab
- Reckitt Benckiser
- RIKILT
- Shimadzu Scientific Instruments, Inc.
- Silliker, Inc.
- Sunshineville Health Products
- SUPELCO/Sigma-Aldrich
- Thermo Fisher Scientific
- TNO Triskelion
- US Dairy Export Council
- US FDA
- US Pharmacopeia
- Waters Corporation

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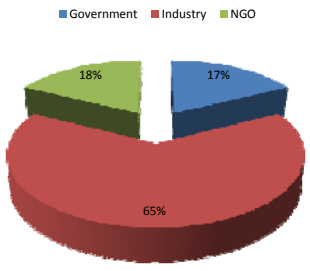
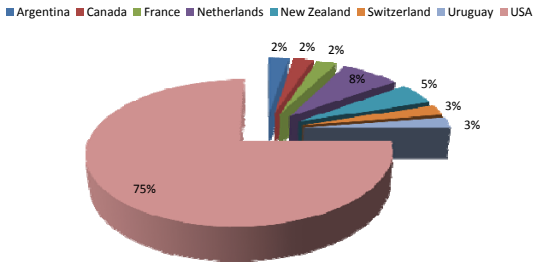
SPIFAN Meeting Registrants

Registrants by Broad Perspectives



Registrants by Region



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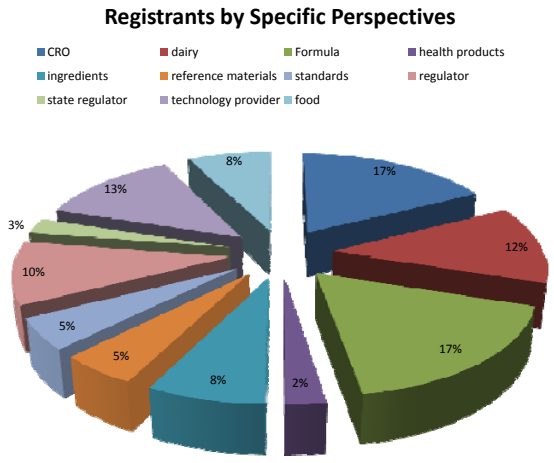
SPIFAN Meeting Registrants



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Representative Voting Members

- Academia/Research
  - Oregon State University
- Government
  - CFIA
  - NIST
  - FDA
  - LATU
  - INTI
  - RIKILT
  - Florida Department of Agriculture
- NGO
  - National Milk Producers Association
  - US Pharmacopeia
  - Infant Nutrition Council of America
  - International Dairy Federation
  - ISO
  - NSF International
- Industry
  - Abbott Nutrition
  - Fonterra
  - Mead Johnson
  - Nestlé
  - Archer Daniel Midland
  - General Mills/Medallion Labs
  - AB SCIEX
  - Mérieux NutriSciences (Silliker)
  - Shimadzu
  - Thermo Fisher Scientific
  - Waters Corporation

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AOAC Stakeholder Panel Role and Responsibilities

- To form working groups to draft SMPR(s) based on specific priorities as specified by the Advisory Panel
- To provide comments on draft standard method performance requirements
- To respond to calls for methods and calls for experts as applicable or appropriate
- Most importantly, share your perspective.
  - To attend stakeholder panel meetings and deliberate on and adopt voluntary consensus standards

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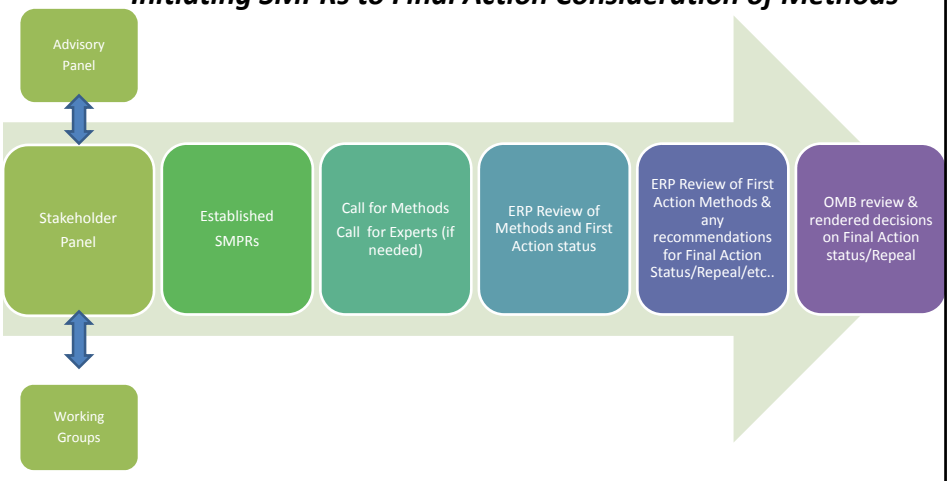
AOAC Standards Development

Initiating SMPRs to Final Action Consideration of Methods



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Products Resulting from SPIFAN Activities Since 2011

- Voluntary Consensus Standards
  - 24 Standard method performance requirements (SMPRs) covering more than 65 nutrient analytes since 2011
  - 4 draft standard method performance requirements
- Fit for Purpose Methods
  - 42 First Action methods adopted/published as in *Official Methods of Analysis of AOAC INTERNATIONAL*
  - 6 First Action methods repealed
  - 6 First Action methods promoted to Final Action status

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Stakeholder Panel Working Groups

- Present background and history on nutrient methods for stakeholder panel
- Develop draft SMPR
- Will present motions to the stakeholder panel on components of the standard method performance requirements
- Can participate in SPIFAN related in-person meetings

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SPIFAN Working Groups

WG on Vitamin A	Jon DeVries	WG on Whey protein: Casein	Lei Bao & Shane Rutherfurd
WG on Vitamin D	Don Gilliland	WG on Fatty acids	Mark Hill
WG on Vitamin B12	Esther Campos-Gimenez	WG on Minerals & Trace Elements	Eric Poitevin
WG on Folic acid	Erik Konings	WG on Biotin	George Joseph/Jean-Luc Deborde
WG on Inositol	Karen Schimpf & Harvey Indyk	WG on Vitamin K	Sneh Bhandari
WG on Vitamin E	Jon DeVries	WG on FOS/GOS	Sean Austin
WG on Nucleotides	Brendon Gill	WG on Amino acids	Wesley Jacobs & Ping Feng
WG on Ultra Trace Minerals	Joe Thompson	WG on Carotenoids	Greg Hostestler
WG on Vitamin C	Jayasharee Arcot & Lalitha Gowda	WG on Fluoride and Chloride	Christopher Blake
WG on Choline	Sneh Bhandari & Rajesh Girdhar/ Nick Cellars	WG on Vitamins B_1, B_2, B_3, and B_6	Louis Salvati
WG on Pantothenic acid	Shang-Jing Pan	WG on SPIFAN Reference Materials	Dan Schmitz/Wayne Wargo
WG on Iodine	Darryl Sullivan	WG on SPIFAN Pesticide Contaminants	Joe Boison
WG on Carnitine	John Austad & Guenther Raffler		

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Standard Method Performance Requirements

- ***Commonly referred to as - SMPRs***

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SMPRs

- Documents a community's analytical method needs
- Very detailed description of the analytical requirements
- Includes method acceptance requirements
- Used to qualify methods for AOAC approval in the *Official Methods*^{SM} program
- Published as a standard

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Performance requirements parameters for quantitative methods

- Analytical range
- Limit of detection
- Limit of Quantitation
- Repeatability
- Recovery
- Reproducibility

4. Method Performance Requirements

Analytical range	0.01–5.0[a]	
Limit of detection (LOD)	≤0.004[a]	
Limit of quantitation (LOQ)	≤0.01[a]	
Repeatability (RSD_r)	0.01[a]	≤15%
	0.2[a]	≤7%
	0.5[a]	
	5.0[a]	
Recovery	0.01[a]	90–110%
	0.2[a]	
	0.5[a]	
	5.0[a]	
Reproducibility (RSD_R)	0.3	≤11%
	0.6	
	1.0	
	2.5	
	5.0	
Concentrations apply to (*1*) "ready-to-feed" liquids "as is"; (*2*) reconstituted powders (25 g into 200 g water); and (*3*) liquid concentrates diluted 1:1 by weight.		
[a] µg/100 g expressed as cyanocobalamin in reconstituted final product.		

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Documentation and Communication

- AOAC will carefully document the proceedings of the stakeholder panel and the working groups
- AOAC will prepare summaries of the proceedings
  - Communicate summaries to the stakeholder panel
  - Publish summaries in the Referee section of AOAC's *Inside Laboratory Management*
- AOAC posts draft standards for comment
- AOAC issues calls for experts (for ERPs)
- AOAC issues call for methods (for candidate method authors)

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ERP Overview

- ERP reviews all methods and adopts methods as First Action *Official Methods of Analysis*
- ERP tracks methods for two (2) years
  - ERP determines which method will be recommended for Final Action *Official Methods* status to the AOAC Official Methods Board
- ERP reviews any additional information on the method including user feedback

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Working Group (WG) Initiative

- AOAC Board of Directors initiates WG Initiative on December 9, 2014
- Individual or entity who expresses a need for a method
- WG may be funded and formed with assistance of AOAC
- WG will develop SMPR to present to an existing stakeholder panels for review

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Why the new WG Initiative?

- Offers companies the opportunities to solve challenges without waiting on priorities of existing stakeholder panels
- WG's funded by current OA's and new companies interested in solving problems

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Measuring Low Level Pesticides in Infant Formula

- Tuesday, March 10, 2015 – News released information regarding eco-terrorist threat to infant formula
  - In New Zealand.
  - Sodium fluoroacetate (Compound 1080)

- In response to this over the last eight days, AOAC has
  - formed a stakeholder panel working group;
    - Initial sponsorship through Abbott Nutrition following AOAC Working Group Initiative
  - Notified the community;
  - Formed an ERP;
  - Issued a call for methods and experts; and
  - Collected methods for Compound 1080

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SPIFAN Related Activities at AOAC Annual Meeting

- SPIFAN WG Meeting for Pesticide Contaminants
  - Monday, March 16, 2015 at 9:00pm – 1:00pm

- SPIFAN Meeting
  - Tuesday, March 17, 2015 at 8:30am – 3:30pm.
    - Deliberation on draft SMPRs for B_1, B_2, B_3 and B_6
      - (last set of nutrients to be launched under second agreement between AOAC and IFC)
    - Deliberation on SMPRs for Sodium fluoroacetate in Infant formula
    - Presentation and Discussion on proposed SPIFAN Ingredient Program and dairy ingredients
    - Updates on SPIFAN and industry related activities

- AOAC ERP on SPIFAN Pesticide Contaminant Methods
  - Tuesday, March 17, 2015 at 4:00pm – 7:00pm
    - Consideration of methods for AOAC First Action Official Methods status

- AOAC ERP on SPIFAN Nutrient Methods
  - Wednesday, March 18 2015 at 8:30am – 5:00pm
    - Consideration of methods for AOAC First Action Official Methods status
    - Consideration of the AOAC First Action Official Methods for Final Action recommendation

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Contact Information

SPIFAN Chair:

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Delia Boyd – Program Manager, Standards Development, dboyd@aoac.org, (301) 924-7077 x126

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STAKEHOLDER PANEL ON INFANT FORMULA & ADULT NUTRITIONALS (SPIFAN)

WHEY PROTEIN UPDATE

Darryl Sullivan
AOAC INTERNATIONAL
Gaithersburg, Maryland, USA
March 17, 2015

1

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Background

- National Food Safety Standard: Infant Formula (GB 10765-2010) – 2012
- Protein and indispensable amino acid requirements
- Whey protein in milk-based formula should be no less than 60%
- Lack of standardized methodology

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Background

- May 24-25, 2012; China Section, Yantai, China; to collect methods from China.
- June 18 -22, 2012, Rockville, MD, approved SMPR for Whey Protein **2012.002.**

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Background cont…

- October 2, 2012, Las Vegas, approved 2-Amino Acid-based Methods (Wyeth and Abbott) as First Action status, **2012.07** and **2012.08**.
- These methods were shown to not be acceptable for dispute resultion

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GB Whey Protein Methods

- AOAC ERP reviewed the LC MS-MS China GB method for the determination of whey protein
- Comments were issued by the ERP for method improvements.

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Next Steps

- January/February 2013 - TLA Meeting, visited with Mr. Zhutian – CFSA in Beijing, China.
- August 2013, Chicago, IL - ERP agreed to send update to Mr. Zhutian – CFSA for input.

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Summary of Whey Protein

- It was thought that the China regulation may be drop and eliminate the need to move forward for a 60% whey requirement
- No progress was made on the GB method since June 2013

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China Activities 2015

中 华 人 民 共 和 国 国 家 标 准

National Standard of the People's Republic of China

GB 5413.xx-201x

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Whey Protein – 2015

- In January the GB Expert Committee passed the LC MS-MS for use in China
- Method was scheduled to be finalized in April 2015
- This would be the dispute resolution method in China

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Industry Reaction

- INCA submitted method comments from infant formula companies
- EUCCC submitted method comments and held a meeting at CFSA
- The finalization of this GB standard has been delayed until June 2015

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AOAC China Section

- Meeting in Suzhou China – April 23-24, 2016
- Erik Konings and Darryl Sullivan will attend from AOAC SPIFAN
- China Experts:
  - Mr. Liu Jinfeng, General Director of China National Center for Food Safety Risk Assessment
  - Professor Ren Yiping, Zhejiang Provincial Center for Disease Control and Prevention

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Next Steps

- Erik Konings, Darry Sullivan, Lei Bao to meet with Professor Ren Yiping, Zhejiang and Liu Jinfeng
- We hope to have a formal meeting for information exchange.
- We also plan some informal dialog to help us understand the situation in China

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Contact Information:

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AOAC® Standards Development and Official Methods of Analysis Overview

Deborah McKenzie, רב
AOAC INTERNATIONAL,
Sr. Director, Standards Development &
AOAC Research Institute

March 2015

AOAC INTERNATIONAL HEADQUARTERS
2275 Research Boulevard, Suite 300
Rockville, Maryland 20840, USA

About AOAC INTERNATIONAL

AOAC is a scientific standards development association dedicated to analytical excellence.

- ~ 3000 members worldwide including **organizational affiliate members**
  - 1/3 of members overseas
- Established a wholly owned subsidiary – AOAC Research Institute
  - administers AOAC conformity assessment programs
- Maintains 16 active international sections representing over 90 countries
- Develops voluntary consensus standard method performance requirements (SMPRs)
- Publishes the *Official Methods of Analysis of AOAC INTERNATIONAL*
- Maintains an accredited Laboratory Proficiency Testing Program
- Governed by a membership-elected volunteer Board of Directors

AOAC® INTERNATIONAL (AOAC) is an independent third-party international standards developing organization and AOAC has no vested interest in the development of standards or in the evaluation of methods of analysis.

About AOAC INTERNATIONAL

AOAC leverages its networks to gather stakeholders and experts to:

- Develop international voluntary consensus standards method performance requirements
- Discuss & adopt methods that are published in the *Official Methods of Analysis of AOAC INTERNATIONAL* using judgment of the world's leading experts.

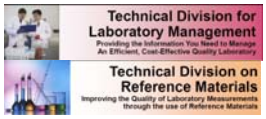
Providing fit for purpose methods through standards development

● *General Locations of AOAC stakeholder panel participants* ● *General Locations of the 16 AOAC INTERNATIONAL current Sections*

About AOAC INTERNATIONAL

- AOAC offers a number of resources through its goods and services; however, AOAC does not:
  - Regulate products
  - Buy or sell food, beverage products, or proprietary technologies
  - Promote specific food and beverage products
  - Set tolerance levels
  - Own a laboratory or provide laboratory services

About AOAC INTERNATIONAL - Resources



Analytical Communities

AOAC's Proficiency Testing Program

SMPR℠

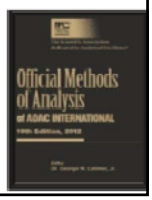
AOAC Mid-Year Meeting

AOAC Annual Meeting & Exposition

EDUCATE NETWORK COLLABORATE

AOAC RESEARCH INSTITUTE

PERFORMANCE TESTED AOAC RESEARCH INSTITUTE
LICENSE NUMBER 000000

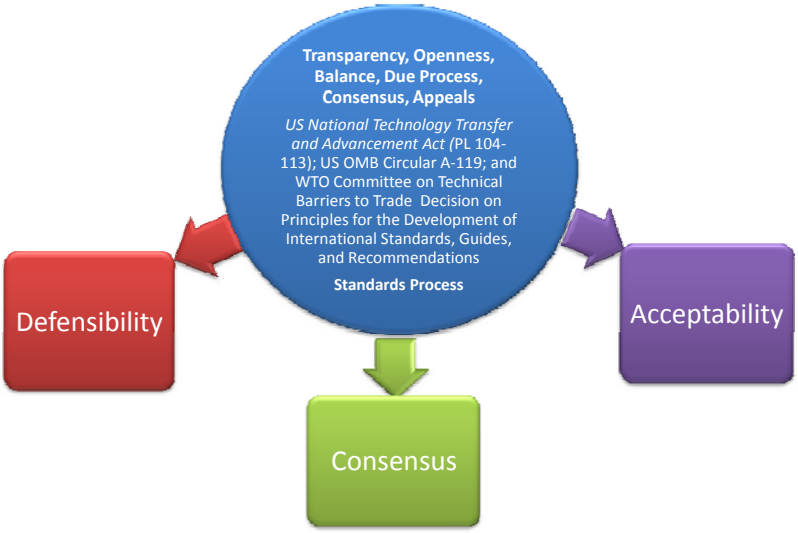


About AOAC INTERNATIONAL - Power of Many

As a scientific association, AOAC *brings scientists together to do a job together that they should not do alone.*

- AOAC leverages its global networks and the value of its independent third party status to provide opportunities for scientific stakeholder groups to *talk about methods* driven by the need for reliable, scientifically valid, fit for purpose methodology.
- Reliable, scientifically valid, fit for purpose methodology are attained by beginning with the development of voluntary consensus standards.
- Methods deemed that meet the voluntary consensus standard are considered fit for purpose and are adopted and published in the *Official Methods of Analysis of AOAC INTERNATIONAL.*

AOAC Creates International Standards



AOAC INTERNATIONAL

As an international standards development organization, AOAC maintains the following principles throughout all standard setting activities:

Transparency

Openness

Balance of Interests

Due Process

Consensus

Appeals

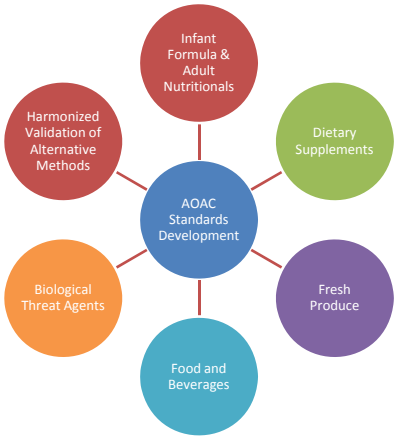
Accomplishments

77	**The number of new fit for purpose First Action methods adopted and published in the *Official Methods of Analysis of AOAC INTERNATIONAL* since 2011**
11	The number of First Action OMA adopted through the AOAC Research Institute since 2013
47	**The number of AOAC voluntary consensus standards developed since 2010**
65	The number of analytes covered by AOAC voluntary consensus standards since 2010
35	The number of analytes for which AOAC voluntary consensus standards are currently in development
12	The number of working groups in process for drafting AOAC voluntary consensus standards
7	The number of working groups being launched in 2015
>230	The number of methods processed and reviewed by AOAC ERPs

ISO and AOAC Sign Cooperation Agreement for Joint Development and Approval of Common Standards
(for milk and milk products)

How does AOAC do this?

- Active AOAC stakeholder panels cover a range of topics including



Advisory Panel*
Stakeholder Panel*
Working Group*
Expert Review Panel*
AOAC Official Methods Board
AOAC Board of Directors

**Managed by AOAC Staff*

AOAC Advisory Panels

Works with staff to:

- Identify key stakeholders
- Identify subject matter experts
- Frame issues & set priorities for standards development
- Facilitate financial support
- Stakeholder Panel Chair moderates panel discussions

Working Group (WG) Initiative

- December 2014, AOAC Board of Directors initiates WG Initiative
  - as an a mechanism for AOAC Organizational Affiliate members to initiate relevant standard development projects using existing AOAC stakeholder panels
    - Expressed a need for a consensus standards and scientifically valid fit for purpose consensus methodology
    - WG supported through AOAC Organizational Affiliates funded and formed through AOAC staff
    - AOAC works with Organizational Affiliates to find additional Organizational Affiliates with the same need for scientifically valid fit for purpose methodology
  - WG will develop SMPR to present to an existing stakeholder panels for review

Why the new WG Initiative?

- Offers companies the opportunities to solve challenges without waiting on priorities of existing stakeholder panels
  - Advisory Panel participation and discussion
- WG's funded by current OA's and new companies interested in addressing immediate needs
  - for analytical standards/standard method performance requirements; and
  - scientifically valid fit for purpose methodology.

Stakeholder Panel Composition

- Product Manufacturers
- Analyte/Method Subject Matter Experts
- Technology Providers
- Method Developers
- Government and Regulatory Agencies
- Contract Research Organizations
- Reference Materials Developers
- Ingredient Manufacturers
- Method End Users
- Academia
- Non-Governmental Organizations (ISO, IDF, etc…)
- Other…. as identified

Anyone with a material interest can participate
Balanced group of voting stakeholders
Chair and voting members vetted

AOAC Stakeholder Panels

- To deliberate on priorities that result in reaching consensus on AOAC voluntary consensus standards
  - Chair of Stakeholder Panel vetted by the AOAC Official Methods Board and appointed by the President of AOAC.
  - Representative Stakeholder Voting Panel members vetted by AOAC Official Methods Board to ensure balance of perspectives represented in determining consensus.
  - Anyone with a material interest can participate in stakeholder panel deliberations.
- Stakeholder Panel form working groups and uses working groups to develop draft standards.
- Working group chair presents standard to stakeholders.

Stakeholder Panels – Voting Panel

- To demonstrate consensus of the stakeholder panel
- Organizations do not have permanent seats or appointments on any given stakeholder panel
  - Balance of Perspectives driven
- Voting panel is determined for each meeting of a stakeholder panel using those registered for a stakeholder panel meeting
  - Vetting through AOAC Official Methods Board

Working Groups

- Chair approved/appointed by Stakeholder Panel chair
- Engage in the detailed discussions and work of the stakeholders
- Develop draft fitness for purpose and standard method performance requirements (SMPRs) or other draft standard as proposed by stakeholder panel
- Recommend draft standards to the stakeholder panel
- Managed by staff

Standard Methods Performance Requirements (SMPRs)

AOAC SMPR 2011.006

Standard Method Performance Requirements for Folate in Infant Formula and Adult/Pediatric Nutritional Formula

- Documents a stakeholder community analytical method needs.
- Very detailed description of the analytical requirements.
- Includes method acceptance requirements.
- Used to adopt AOAC Official Methods by AOAC Expert Review Panels.
- Published as a standard.

After SMPRs are Approved

AOAC *Official Methods of Analysis*℠

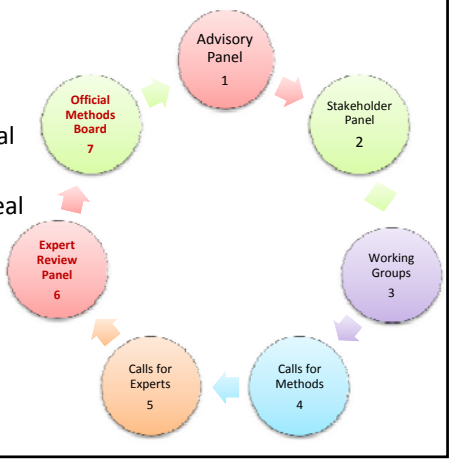
- AOAC issues a Call for Methods
  - Using the stakeholder voluntary consensus SMPR
- AOAC issues a Call for Experts
  - Establish an AOAC Expert Review Panel to review methods for AOAC Official

AOAC Expert Review Panel (ERP)

- All candidates are vetted by AOAC Official Methods Board (OMB)
- Approved members are appointed by President of AOAC
- ERP member must go through ERP Orientation
- ERP Review methods for AOAC First Action *Official Methods* status
- Adopt methods as AOAC First Action *Official Methods* status
- Tracks First Action methods for 2 years after adoption

Final Action *Official Methods*

- During the Tracking Period:
  - ERP reviews any information on reproducibility, user feedback, etc.. using guidance by AOAC OMB (OMA, Appendix G)
- When ERP has sufficient information it can:
  - Make a recommendation for Final Action Official Method status
  - Make a recommendation to repeal the Official Method
- Official Methods Board
  - Reviews ERP recommendations and renders decisions on Final Action status or repeal



Documentation and Communication

- AOAC carefully documents the actions of Stakeholder Panel and the Working Groups
- AOAC will prepare summaries of the meetings
  - Communicate summaries to the stakeholders
  - Publish summaries in the *Referee* section of AOAC's *Inside Laboratory Management*
- AOAC publishes its voluntary consensus standards and Official Methods
  - *Official Methods of Analysis of AOAC INTERNATIONAL*
  - *Journal of AOAC INTERNATIONAL*
- AOAC publishes the status of standards and methods in the Referee section of AOAC's *Inside Laboratory Management*

AOAC Process and Compound 1080

- Using the AOAC WG Initiative
  - Organizational Affiliate had an immediate need for SMPR and consensus scientifically valid fit for purpose methods for sodium fluoroacetate in infant formula.
  - AOAC, OA, Advisory Panel and Stakeholder Panel chair conferred on establishing working group
  - AOAC leverages its SPIFAN and its standards development process to address the need.
  - AOAC is using a Quality Assurance Surveillance Plan (QASP) as a way of tracking that all process steps taken are in accordance with AOAC's policies and procedures

Modifications to Typical Process

- Develop draft standard in advance of stakeholder panel launch.
- Present background and draft SMPR during the SPIFAN meeting
  - Stakeholders will be asked to demonstrate consensus on draft SMPR prior to posting SMPR.
    - Posting SMPR for comments will follow AOAC Mid Year meeting
    - Comments received will be reconciled and presented during AOAC SPIFAN meeting in September.
  - Call for Methods will be reissued using the SMPR
    - Any additional methods received will be reviewed during an ERP meeting in September.

Questions?

Thank you.

STAKEHOLDER PANEL ON INFANT FORMULA AND ADULT NUTRITIONALS (SPIFAN)

Louis Salvati, Abbott Nutrition
Vitamins B_1, B_2, B_3 & B_6 Working Group Chair

Louis M. Salvati is originally from the Pittsburgh, PA area and attended the University of Pittsburgh at Johnstown where he received his B.S. in chemistry in 1991.

He also attended The Ohio State University where he worked under Professor Prabir K. Dutta in the area of applications of micro-porous materials such as zeolites and clays. He received my MS from OSU in 1993.

Dr. Salvati began his work at Abbott Laboratories-Nutrition division in 1996 in the vitamin testing lab and has been in the R&D vitamin testing area his entire career at Abbott serving in various capacities and has attained expertise with several water and oil soluble vitamins. He also has extensive experience with many testing technologies such as HPLC, and mass spectroscopy.

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Approval of SMPR for:
Vitamins B_1, B_2, B_3 and B_6

Louis Salvati
Columbus, OH, USA

March 17, 2015

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Agenda

- **Review**
  - SMPR
  - Comments / Responses
- **Motion to Adopt SMPR**

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Analyte Definition

- **Description of the analyte:**

  Determination of content of Vitamins B_1, B_2,B_3,and B_6. Total vitamin content consists of all free forms of each nutrient and all common phosphorylated forms.

- **Rationale:**
  - Common fortified forms are Thiamine chloride, Riboflavin, Nicotinamide, and Pyridoxine.
  - Other common inherent forms are Thiamine mono, di and triphosphate, FMN, FAD, Nicotinic Acid, Pyridoxal, Pyridoxal 5' phosphate, Pyridoxamine, and Pyridoxamine 5' phosphate.

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Specific Performance Claims B_1

Analytical range	30 – 2000 µg /100 g
Limit of Quantitation (LOQ)	≤ 30*
Recovery	90-110%
Repeatability (RSDr)	≤ 5%
Reproducibility (RSDR)	≤10%

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Specific Performance Claims B_2

Analytical range	40 – 4000*
Limit of Quantitation (LOQ)	≤ 20*
Recovery	90-110%
Repeatability (RSDr)	≤ 5%
Reproducibility (RSDR)	≤ 10%

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Specific Performance Claims B_3

Analytical range	200 – 10000*
Limit of Quantitation (LOQ)	≤ 200*
Recovery	90-110%
Repeatability (RSDr)	≤ 5%
Reproducibility (RSDR)	≤ 10%

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Specific Performance Claims B_6

Analytical range	20 – 2000*
Limit of Quantitation (LOQ)	≤ 20*
Recovery	90-110%
Repeatability (RSDr)	≤ 5%
Reproducibility (RSDR)	≤ 10%

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Specific Performance Claims

- **Repeatability**:
- **Recovery**:
- **Reproducibility**:

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Stakeholder Comments

Original Comment	Proposed Change	My response
The mode of expression of the B3 result is not precised	Total B3 is the sum of nicotinic acid and nicotinamide. All data should be mass corrected and expressed as nicotinic acid	I would agree that all Vitamin B3 data must be mass corrected and reported consistently. I would also agree that the reported form should be Nicotinic Acid. The correction should be to footnote 1 as follows: *Total B_3 defined as the sum of Nicotinic Acid and Nicotinamide.* ***Total B_3 should be expressed as the Nicotinic Acid form.***
In the other SMPR the lower value of the analytical range is equal to the limit of quantification. For riboflavin it is not the case	Change the lower value of the analytical range to 20 or change the LOQ to 40	I agree LOQ for B2 should be raised to 40.

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Stakeholder Comments

Original Comment	Proposed Change	My response
The formula of thiamin, as the chemical structure, is an ion (M=265,37) a lot of regulations use thiamine chloride (M=300,82). some databases use thiamine chloride, hydrochloride (M=337,28) The CAS number of line 56 (59-43-8) is the CAS of thiamin chloride. The CAS number of thiamine chloride, hydrochloride is 67-03-8?	to be precised by the review panel. In EU it is often thiamin choride (M=300,82) CAS number 59-43-8	I believe this was discussed and the consensus was to report Thiamine as the ion to avoid any confusion. I agree the CAS number should be corrected to reflect the ion form which is 70-16-6. As for footnote 1 it may also be wise to modify by stating thiamine ion. The SRM value is stated in the correct units.

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Original Comment	Proposed Change	My response
Method name: although many of the SMPR already issued are intended to be applicable to "total" vitamin, this has not been set up in the title, but rather in the definition 1. Applicability: For consistency and alignment with other SMPRs already published. Add definition as stated in other SMPRs instead of in a footnote 2. Definitions: Accuracy has never been defined as such previously, the definition of "recovery" has always been present instead. Keep consistency	Method name: Determination of vitamin XX (XX) in..... 1. Applicability: Add: "For the purpose of this SMPR, vitamin XX is defined as the sum of xxxx". Include CAS numbers for each compound using same format as other SMPRs already published (example: choline, C, B12, A, D) 2. Definitions: use same format and contents as other SMPRs in SPIFAN. Remove definition of the vitamin in this section, include in section 1. Applicability. Remove chemical structures, as this can easily be found if CAS numbers are included. If they absolutely have to be present, include them in an Annex or at the end of the document, as in the example of carotenoids. 4. Method performance requirements: low limits given in the requirements are at the same level or higher than minimum Codex levels. Please review, this has been extended to 50 % of minimum level for other SMPRs, or even lower in some specific cases and when justified. Technical comments: we have questions on the inclusion of all possible natural forms of the vitamins, knowing that not all are present in the type of matrices in the scope of the project. 5 % and 10 % for RSDr and RSDR might be tight	I will comment on this in parts. I do agree that footnote 1 in each SMPR should be included in the Applicability section with the preface " For the purpose of this SMPR…" Additionally all CAS numbers should be included. I do not have an issue with moving vitamin definition to section one, and removing structures. Unless the change was made for specific reasons which I am not aware of I have no problem with making the Accuracy definition consistent, and adding recovery. I don't believe sensitivity will be major issue with any of these analytes therefore I am comfortable reducing the lower range to up to 50% of the Codex limits. I believe the RSDs are achievable. Including all forms was discussed and agreed upon, and several objections were noted. However the final concensus was the forms stated in the SMPRs

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Stakeholder Comments

Original Comment	Proposed Change	My response
	I think NAD/NADH should be included in SMPR, maybe it was overlooked? If NAD(H) was considered and rejected as unimportant then the SMPR should state this, rather than ignoring its contribution. FMN/FAD is mentioned for vitamin B2, and the phosphate coenzymes of B1 and B6, so the innate coenzyme forms are potentially an issue for SPIFAN	I don't believe these forms were discussed much at the September meeting. At this time due to the negligible concentrations of these forms, and the fact that both alkali, and acid hydrolysis will easily liberate both forms to one of the measured forms I would leave the SMPR as is.

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Motion for Approval

I move for SPIFAN to approve the SMPR for (Nutrient).

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Questions??

STAKEHOLDER PANEL ON INFANT FORMULA AND ADULT NUTRITIONALS (SPIFAN)

Murali Reddy, Abbott Nutrition

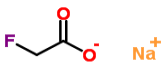
Dr. Murali Reddy is currently heads "the Food Safety and Analytical Research group" at Abbott Nutrition International. His active research interests include the development of novel analytical methods for the sensitive detection of chemical contaminants in food ingredients and application of hyphenated analytical techniques to support nutritional and biological analyses. Murali holds an M. Sc., degree in chemistry from the Meerut University in India. Murali also holds an M.S., degree in organic chemistry from the University of Idaho. Murali's previous work experience includes fifteen years of pharmaceutical drug discovery and development and has been with Abbott since 2012.

A high throughput quantitative and confirmatory method for the analysis of monofluoroacetate in nutritional products by liquid chromatography-mass spectrometry

Nick Cellar, Stefan Ehling, and Murali Reddy

March, 2015

MONOFLUOROACETATE SODIUM



- Molecular Formula: $C_2H_2FNaO_2$ Average mass: 100.024 Da
- Sodium fluoroacetate is a fluffy white material at room temperature, which forms colorless solutions with water and is normally odorless.
- Used to control wild dogs, feral pigs, foxes, cats, possums and rabbits in New Zealand and Australia
- Occurs naturally in a number of native plant species including Acacia georginae (Georgina gidgee) and members of the Gastrolobium and Oxylobium genera.
- Fluoroacetate interferes with the citric acid (Krebs) cycle. Known toxicity to carnivores (dogs)/herbivores (cattle)/omnivores (pigs)
- The LD50 value for cattle is 0.4 mg/Kg body weight

MONOFLUOROACETATE ANALYSIS METHODS

- A wide range of analytical approaches
  - Direct analysis (LC-UV, CE-UV, IC-PAD-ICP-MS)
  - Derivatization analysis (GC-MS, LC-MS)
- Matrices
  - Drinking water
  - Sheepskin and wool
  - General foods
    - Tuna fish
    - Green peas/Baked beans
    - Peanut butter
    - Ice cream
    - Coffee/Fruit punch

DIRECT VS DERIVATIZATION ANALYSIS METHODS

- Direct analysis method
  - Simple to use
  - Prone to sensitivity and intereferences issues
- Derivatization method
  - Excellent specificity and sensitivity
  - Complex and time consuming procedures
  - Matrix specific procedures

METHOD REQUIREMENTS FOR NUTRITIONAL PRODUCTS ANALYSIS

- Rapid, easy to use quantitiave method
- Simple to use with existing laboratory instrumentation
- Quantitative and high degree of selectivity
- Confirmatory technique
- Primary method supported by a secondary confirmatory method
- Primary method is “direct” analysis
- Secondary method is “derivatization” based analysis
- Applicable to milk based nutritional products

FDA PUBLICATION (NOONAN, BEGLEY, DIACHENKO)

Available online at www.sciencedirect.com
ScienceDirect
Journal of Chromatography A, 1139 (2007) 271–278

JOURNAL OF CHROMATOGRAPHY A
www.elsevier.com/locate/chroma

Rapid quantitative and qualitative confirmatory method for the determination of monofluoroacetic acid in foods by liquid chromatography–mass spectrometry

G.O. Noonan *, T.H. Begley, G.W. Diachenko

US Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, College Park, MD 20740, USA

Received 14 September 2006; received in revised form 8 November 2006; accepted 10 November 2006
Available online 1 December 2006

FDA PUBLICATION (2007)

- LC-MS based "primary" quantitiave method
- Simple to use with existing laboratory instrumentation
- Quantitative and specific
- Primary method supported by a secondary confirmatory method
- Secondary method is "derivatization" based analysis (2-NPH)
- Secondary method is "qualitative"
- Not shown to work with milk based nutritional products

MILK PRODUCTS METHOD DEVELOPMENT GOALS

- LC-MS based "primary" quantitiave method
- Quantitative and specific (2 MRM transitions)
- Simplified sample preparation scheme (protein precipitation)
- Primary method supported by a secondary confirmatory method
- Secondary method is "derivatization" based analysis (2-NPH)
- Secondary method is "quantitative" (1 MRM transition)
- Show applicability with milk based nutritional products
- Multi day method performance data (2 labs, 2 LC-MS platforms)
- Target concentation of 30 ppb in powders

"DIRECT" ANALYSIS METHOD

LC-MS CONDITIONS

- The FDA publication used:
  - RP C 18 + ion pairing conditions (TBA)
  - APCI conditions, negative ionization mode
  - Single MRM transition
- Our approach
  - Multi mode ODS column +non ion pairing conditions
  - ESI, negative ionization mode
  - Two MRM transitions
  - Summation of two transitions for quantitation

CHROMATOGRAPHY

- Multimode ODS column:
  - Scherzo SS-C18 column (100 x 3 mm)*
  - Purified Porous Silica / Particle Size 3um / Pore Size 13nm / ODS + Anion Exchange + Cation Exchange Ligands
  - Separation achieved through a manipulation of eluent pH, organic solvent composition, salt concentration, and temperature.
  - Enables the retention of ionic species with LC-MS compatible mobile phases
  - Avoids the use of ion pairing agents in mobile phases
  - Provides simple and rugged chromatographic retention

* = Imtakt USA, Portland, OR

SAMPLE PREPARATION

- **For powders:**
  - Weigh 10.0 ± 0.5 g of powder into a tared vessel and record mass.
  - Add water to a total weight of 70 ± 5 g (powder + water) and record mass.
  - Stir until homogenous.
- **For ready-to-feed liquids and reconstituted powders:**
  - Weigh 5.00 ± 0.20 g liquid into a tared 15 mL centrifuge tube and record mass.
  - Add 40 µL of internal standard working solution and vortex.
  - Add 50 µL of glacial acetic acid and 5.0 mL methanol, vortex.
  - Transfer aliquot to microfuge tube and centrifuge at 13,000 rpm for 10 min.
  - Filter an aliquot of the supernatant into an autosampler vial using a 0.2 um PTFE syringe filter.

LC CONDITIONS

Mobile Phase A: 0.1% formic acid in water

Mobile Phase B: 0.2% formic acid in methanol

Chromatography				
Flow Rate	350 µL/min			
Column Temperature	40°C			
Injection Volume	5 µL			
Sample Temperature	Ambient			
Gradient Program	Time	% A1	% B1	Curve
	0.00	100	0	6
	2.00	100	0	6
	6.00	2	98	6
	9.00	2	98	6
	9.01	100	0	6
	11.00	100	0	6

MS CONDITIONS

MS Tune			
Ionization Mode	ESI-	Cone Gas	250 L/Hr
Capillary	2.5 kV	Nebulizer	7.0 bar
Source Offset	30.0 V	Collision Gas Flow	0.15 mL/min
Source Temperature	150°C	Quad 1 Resolution	Unit Mass (0.75 Da FWHM)
Gas Temperature	350°C	Quad 2 Resolution	Unit Mass (0.75 Da FWHM)
Desolvation Gas Flow	900 L/Hr	MS Calibration Range	50-2000 amu

MS/MS Transitions					
Compound	Parent Mass (m/z)	Daughter Mass (m/z)	Dwell (s)	Cone (V)	Collision Energy (V)
MFA 1	77.0	33.0	0.250	20	10
MFA 2	77.0	57.0	0.250	20	10
MFA IS 1	81.0	36.0	0.250	20	10
MFA IS 2	81.0	60.0	0.250	20	10

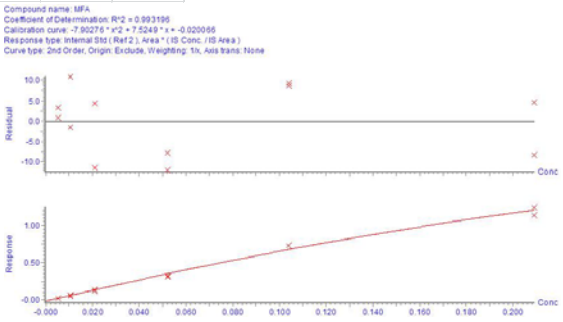
CALIBRATION/QC STANDARDS

Cal Std	MFA (µg/mL)
CS 1	0.005
CS 2	0.010
CS 3	0.020
CS 4	0.050
CS 5	0.100
CS 6	0.200

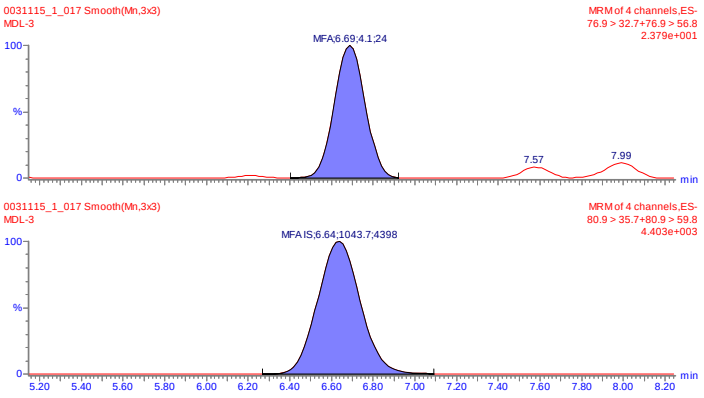
QC Std	In powder (ug/g)	In liquid (ug/g)
MDL	0.03	0.002
QC-L	0.15	0.011
QC-M	0.35	0.025
QC-H	0.70	0.050

STANDARD CURVE DATA (3 DAYS)

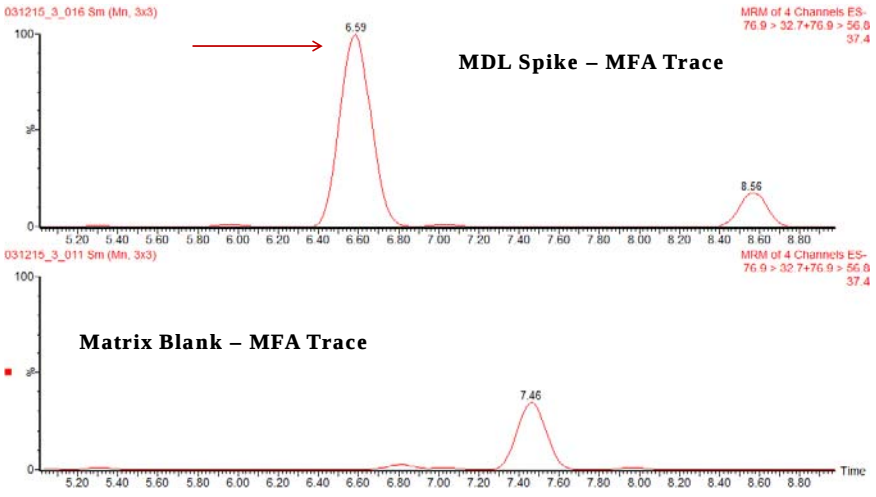
%Accuracy	WS1	WS2	WS3	WS4	WS5	WS6
Day-1						
1	100.8	98.5	104.4	92.2	108.5	91.8
2	103.3	110.7	88.6	87.9	109.2	104.6
Day-2						
1	82.5	117.4	84	93.5	102.8	101.3
2	108.2	126.2	79.6	99.4	108.9	96.3
Day-3						
1	110.3	79.4	103.7	100.5	93.9	106.6
2	104.8	91	110.9	102.2	102.8	94.2



MDL SPIKE CHROMATOGRAM (0.03 ug/g POWDER)



MDL SPIKE – MATRIX BLANK CHROMATOGRAM



"DIRECT" METHOD PERFORMANCE DATA

(3 DAYS ACCURACY/PRECISION DATA)

Day-1	QC - MDL	QC - Low	QC - Med	QC - High
1	135.1	84	77.7	77.8
2	134.7	115.2	85.5	79.5
3	132.2	71.6	72	77
4	147.4	80.9	82.6	81.6
5	157.8	88.9	72.8	71.6
Avg. %accuracy	141.4	88.1	78.1	77.5
SD	10.9	16.4	5.9	3.7
%RSD	**7.7**	**18.6**	**7.6**	**4.8**
Day-2	**QC - MDL**	**QC - Low**	**QC - Med**	**QC - High**
1	81.2	88.3	77.7	101
2	57.6	93	99.6	95.1
3	65.6	80.6	99.6	108.2
4	103.3	129.4	97.1	95.4
5	76.6	99.5	105	106.2
Avg. %accuracy	76.9	98.2	95.8	101.2
SD	17.4	18.8	10.5	6.0
%RSD	**22.7**	**19.1**	**11.0**	**5.9**
Day-3	**QC - MDL**	**QC - Low**	**QC - Med**	**QC - High**
1	129.6	Outlier	102.8	75.1
2	163.6	118.7	82	101.1
3	142.6	107.5	92.5	88
4	145.7	75.7	109.6	110.8
5	137.4	96.9	89.1	94.6
Avg. %accuracy	143.8	99.7	95.2	93.9
SD	12.6	18.3	11.0	13.5
%RSD	**8.8**	**18.4**	**11.6**	**14.3**
3 Day average	120.7	95.0	89.7	90.9
SD	34.6	17.2	12.2	13.1
%RSD	**28.7**	**18.2**	**13.6**	**14.4**

Sample	In powder (ug/g)	In RTF liquid (ug/g)
QC - MDL	0.03	0.002
QC - Low	0.15	0.011
QC - Med	0.35	0.025
QC - High	0.70	0.050

MDL Calculation		
t-value, 99% CI, (N-1) = 13 degrees of freedom		2.624
	SD	0.012
	LOD	0.03 ug/g

METHOD PERFORMANCE DATA – LAB#2

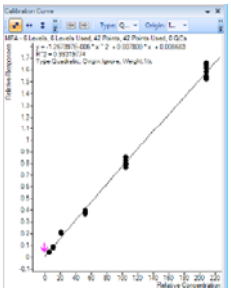
- Run QCs (precision/accuracy)

#	QC - MDL	QC - Low	QC - Med
1	139	122	104
2	131	82	113
3	132	140	93
Avg. %accuracy	134.0	114.7	103.3
SD	4.4	29.7	10.0
%RSD	**3.3**	**25.9**	**9.7**

Standard Curve (accuracy)

STD Conc (ppb)	%Accuracy (Set-1)	%Accuracy (Set-2)
5	118.77	100.76
10	101.97	105.97
25	96.96	100.24
50	95.46	96.57
100	95.70	95.43
200	100.36	97.18

Calibration Curve



"DERIVATIZATION" ANALYSIS METHOD

SAMPLE PREPARATION

- Samples are prepared by dilution in water followed by protein precipitation with acetonitrile.
- An aliquot of the sample extract is derivatized with 2-nitro-phenylhydrazide (2-NPH) in the presence of 1-ethyl-3-(-3-dimethylaminopropyl) carbodiimide hydrochloride (EDC).
- This reaction achieves the coupling of the carboxyl group of monofluoroacetate to the amino group of 2-NPH with the formation of an amide bond.
- Samples are processed through a solid-phase extraction step in order to exchange sample solvent and achieve a 5-fold concentration of the extract.
- A stable-isotope labeled internal standard is incorporated into the sample preparation to correct for instrument response and losses in sample preparation.
- Overall sample dilution of 1:10

LC CONDITIONS

- Waters Acquity ACQUITY UPLC® BEH C18 1.8 µm, 2.1 x 100 mm column
- Mobile phase-A: 10 mM ammonium acetate in water
- Mobile phase-B: 10 mM ammonium acetate in 95/5 (vol.) acetonitrile/water
- Gradient conditions

Chromatography				
Flow Rate	300 µL/min			
Column Temperature	40°C			
Injection Volume	10 µL			
Sample Temperature	Ambient			
Gradient Program	Time	% A	% B	Curve
	0.00	90	10	6
	1.00	90	10	6
	7.00	45	55	6
	9.00	0	100	6
	9.01	90	10	6
	12.00	90	10	6

MS CONDITIONS

MS Tune			
Ionization Mode	ESI-	Cone Gas	250 L/Hr
Capillary	0.5 kV	Nebulizer	7.0 bar
Source Offset	20.0 V	Collision Gas Flow	0.15 mL/min
Source Temperature	150°C	Quad 1 Resolution	Unit Mass (0.75 Da FWHM)
Gas Temperature	350°C	Quad 2 Resolution	Unit Mass (0.75 Da FWHM)
Desolvation Gas Flow	900 L/Hr	MS Calibration Range	50-2000 amu

MS/MS Transitions					
Compound	Parent Mass (m/z)	Daughter Mass (m/z)	Dwell (s)	Cone (V)	Collision Energy (V)
MFA-2NPH	212	182	0.15	20	15
MFA-2NPH_IS	216	186	0.15	20	15

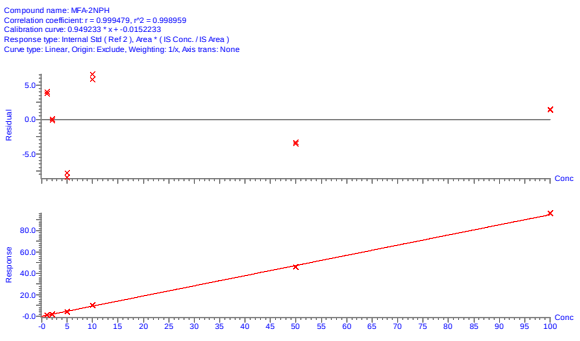
CALIBRATION/QC STANDARDS

CS 1	0.001
CS 2	0.002
CS 3	0.005
CS 4	0.01
CS 5	0.05
CS 6	0.1

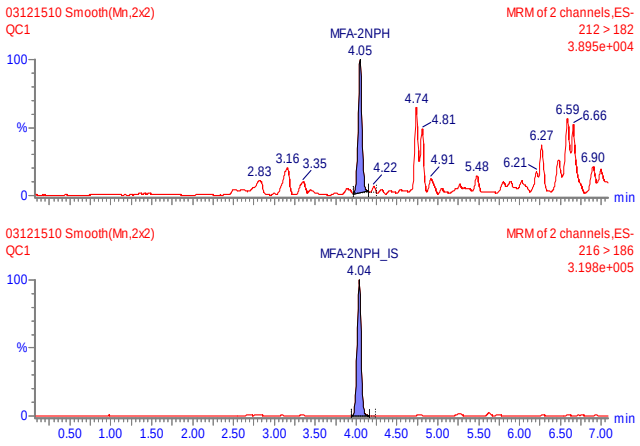
	In powder	In liquid
QC Std	ug/g	(ug/mL)
MQL	0.01	0.001
QC-Low	0.025	0.0025
QC-Med	0.1	0.01
QC-High	0.5	0.05

STANDARD CURVE DATA (3 DAYS)

%Accuracy	WS1	WS2	WS3	WS4	WS5	WS6
Day-1						
1	104	99.9	91.5	105.9	96.5	101.5
2	103.7	100.1	92.2	106.6	96.6	101.4
Day-2						
1	103	98.4	93.3	106.2	97.2	101.5
2	104	100.1	92.2	106.6	96.3	101.2
Day-3						
1	99	101.7	91.7	108.6	97	101.3
2	101.5	101.3	91.6	108.9	96.5	101



MDL SPIKE CHROMATOGRAM (0.01 ug/g POWDER)



"DERIVATIZATION" METHOD PERFORMANCE DATA

(3 DAYS ACCURACY/PRECISION DATA)

Day-1	QC-MDL	QC-Low	QC-Med	QC-High
1	85.6	102.204	88.233	103.8616
2	72.4	98.1	86.176	100.8012
3	82.21	90.444	93.013	95.0276
Avg %accuracy	80.1	96.9	89.1	99.9
SD	6.9	6.0	3.5	4.5
%RSD	8.6	6.2	3.9	4.5

Day-2	QC-MDL	QC-Low	QC-Med	QC-High
1	83.3	101.6	102.3	104.0
2	92.9	101.5	98.6	100.6
3	88.7	99.1	102.4	104.8
Avg %accuracy	88.3	100.7	101.1	103.1
SD	4.8	1.4	2.2	2.2
%RSD	5.5	1.4	2.1	2.2

Day-3	QC-MDL	QC-Low	QC-Med	QC-High
1	84.26	95.532	81.656	91.9238
2	85.2	95.28	82.244	99.1004
3	82	95.6	87.061	96.7278
Avg %accuracy	83.8	95.5	83.7	95.9
SD	1.6	0.2	3.0	3.7
%RSD	2.0	0.2	3.5	3.8
3 Day average	84.1	97.7	91.3	99.6
SD	5.6	3.9	8.1	4.4
%RSD	6.6	4.0	8.9	4.4

Sample	In powder (ug/g)	In RTF liquid (ug/g)
QC-MDL	0.01	0.001
QC-Low	0.025	0.0025
QC-Med	0.1	0.01
QC-High	0.5	0.05

MDL Calculation		
t-value, 99% CI, (N-1) = 8 degrees of freedom		2.896
	SD	0.56
	LOD	1.4 ppb

IMPROVEMENTS MADE TO DERIVATIZATION PROCEDURE

- A protein precipitation step with acetonitrile was included.
- Reagents were prepared according to Miwa et al. (2000), J. Chrom. A 881, 365, which reduces the number of steps involved in the derivatization process. Ibid. for reaction conditions (80 °C, 5 min) which reduces overall sample processing time.
- Excess reagent was not removed. There was no indication that the presence of excess reagent had any adverse effect on the analysis or the instrumentation.
- One single reversed phase SPE step was used for solvent exchange and 5-fold concentration of extract.
- Tandem mass spectrometry (MS/MS) was used which adds another level of selectivity compared to single stage MS.
- Stable isotope labeled internal standard was used for accurate quantitation.

CONCLUSIONS

Direct Analysis Method

- A simple and high throughput LC-MS method has been developed for nutritional products analysis of MFA
- Specificity and quantitation in matrix demonstrated
- 30 ppb quantitation limit in powders
- Implemented for routine analysis at a third part laboratory for samples analysis

Derivatization Method

- A streamlined derivatization method has been developed for nutritional products analysis of MFA
- Specificity and quantitation in matrix demonstrated
- 10 ppb quantitation limit in powders
- Confirmatory method

ACKNOWLEDGEMENTS

- "Direct" Analysis Method
  - Nick Cellar, Stefan Ehling, Jon Draher (Abbott)
  - John Schmitz, John Zulkoski (Covance)
- "Derivatization" Analysis Method
  - Stefan Ehling (Abbott)
- Dan Schmitz, Director, Analytical R&D, AN

Ensuring the Safety and Quality of Ingredients Using Standardized, Harmonized Analytical Methods

Murali Reddy

March, 2015

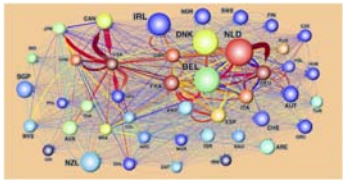
BACKGROUND

COMPLEXITY OF THE INTERNATIONAL AGRO-FOOD TRADE NETWORK

- Highly heterogeneous, complex supply-chain network
- Food trade is growing faster than the food production. By 2030, food demand is expected to increase by 50%
- Trade grew from $438 billions in 1998 to $1060 billions in 2008
- While the total food production grew only 1.4-fold in the same period
- Consequent increase in global sourcing of ingredients, and
- Heightened potential for safety related incidents

Diagram of the international food trade

Ercsey-Ravasz et al., 2012 PLoS One, 7: e37810



CHINA'S YILI RECALLS MERCURY-TAINTED BABY FORMULA MILK (2012) CHINA'S YILI RECALLS MERCURY-TAINTED BABY FORMULA MILK (2012)

15 JUNE 2012 LAST UPDATED AT 08:31 ET

BBC News NEWS CHINA

China's Yili recalls mercury-tainted baby formula milk

A major diary firm in China has recalled some of its baby formula products after an "unusual" level of mercury was found by the country's product quality watchdog.

The company also said in the statement that there is "no benchmark for mercury levels in milk powder products available from China and abroad".

http://www.bbc.co.uk/news/world-asia-china-18456795

Overview of template

AFLATOXIN IN MILK (2013)

4 March 2013, 19:19

Aflatoxin discovered in Dutch milk

http://sputniknews.com/voiceofrussia/2013_03_04/Aflatoxin-discovered-in-Dutch-milk

Overview of template

NITRITE IN MILK POWDER (2013)

REUTERS

Halted China-bound milk powder in May for high nitrite levels

"..said the milk powder showed nitrite levels of between 1.4 parts per million and 1.8 ppm when it was shipped from New Zealand, but showed higher levels in Chinese tests.

"The limit is 2 parts per million in China and the product tested at somewhere between 2.4 ppm and 2.8 ppm,"

http://www.reuters.com/article/2013/08/22/us-china-newzealand-dairy-idUSBRE97L06820130822

Overview of template

DCD IN MILK (2013)

THE WALL STREET JOURNAL.
U.S. EDITION

By LUCY CRAYMER

WELLINGTON—A toxic substance has been found in New Zealand milk, in a potential blow to the nation's dairy exports, which are valued at 11.5 billion New Zealand dollars (US$9.7 billion) annually.

Low levels of dicyandiamide-also called DCD-have been found in New Zealand milk. The chemical, which farmers apply to pastures to reduce greenhouse-gas emissions, is toxic to humans in high doses. The WSJ's Lucy Craymer has the details.

The country's two biggest fertilizer companies, Ravensdown Ltd. and Ballance Agri-Nutrients Ltd., have suspended sales of dicyandiamide, or DCD, after low levels were found in dairy products. Farmers apply DCD to pastures to prevent nitrate, a fertilizer byproduct that can also cause health problems, from getting into rivers and lakes.

Though there are no international standards for the acceptable level of DCD in food products, in high doses the substance is toxic to humans.

Overview of template

QACS (2013-2014)

efsa
European Food Safety Authority

EFSA supporting publication 2013:EN-483

TECHNICAL REPORT

Evaluation of monitoring data on residues of didecyldimethylammonium chloride (DDAC) and benzalkonium chloride (BAC) [1]

European Food Safety Authority[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

Overview of template

ARSENIC IN INFANT FORMULA (2015)

ehp ENVIRONMENTAL HEALTH PERSPECTIVES

CHILDREN'S HEALTH ADVANCE PUBLICATION

Environ Health Perspect; DOI:10.1289/ehp.1408789

Estimated Exposure to Arsenic in Breastfed and Formula-Fed Infants in a United States Cohort

Courtney C. Carignan,[1,2,*] Kathryn L. Cottingham,[1,2,*] Brian P. Jackson,[1,3] Shohreh F. Farzan,[1,4] A. Jay Gandolfi,[5] Tracy Punshon,[1,2] Carol L. Folt,[1,2] and Margaret R. Karagas[1,4]

Overview of template

CHINA GB METHODS FOR INGREDIENTS TESTING

• Nitrite/nitrate	GB5009.33-2010
• Hormones	GB-T 21981-2008
• Tetracyclines	GBT 22990-2008
• Sulfonamides	GBT 22966-2008
• Organo chlorine pesticides	GBT 5009 19-2008
• Mercury and organic mercury	GB T 5009.17-2003
• Aflatoxin M1	GB 5413.37-2010
• As and "abio" As	GB 5009.11-2003
• Lead	GB 5009.12-2010
• Chromium	GB T 5009.123-2003

Overview of template

INDIA FSSAI METHODS FOR INGREDIENTS TESTING

- Organochlorine pesticides
- Total aflatoxins
- Naturally occurring substances
- Heavy metals & methyl mercury

Overview of template

ADVANCES IN ANALYTICAL INSTRUMENTATION

Chloramphenicol:

- Current regulated limit 0.3 ppb (MRPL)
- Detection limit achieved using Bruker UHR-TOF 0.025 ppb*
- 12 fold lower than regulated limits

Improving the limit of quantitation for chloramphenicol using a new ion source on an UHR-TOF

Carsten Baessmann, Karin Wendt, Thomas Zey, Amalia Apalategui, Petra Decker

Bruker Daltonik GmbH, Bremen, Germany, Asilomar, 2012

Overview of template

IN SUMMARY

- Absence of standardized, harmonized analytical methods
- Ever increasing sophistication of analytical instrumentation
- Rapid dissemination of analytical technologies around the globe
- Increasing trade in food ingredients (emerging markets)
- Emerging emphasis on ingredient controls

Overview of template

NET EFFECT IS ..

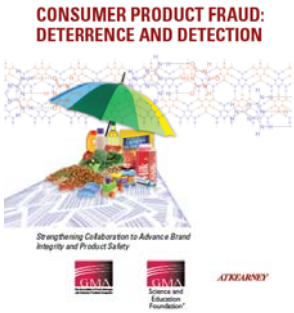
- Heightened safety risks for IF industry
- Increasing regulatory burden for ingredients safety
- Increasing media coverage regarding infant nutritional safety
- Increasing potential for business disruption

Overview of template

COST OF FOOD SAFETY INCIDENTS

- Cost of economic adulteration and counterfeiting of global food and consumer products is $10 - $15 billions/year
- Cost of once incident of product adulteration runs between 2%-15% of annual revenue. Translates to $400 million impact for a $10 billion company

Source: GMA, 2010 study



Overview of template

HOW DO WE MANAGE THE PROBLEM?

- Definition of appropriate testing,
- Standardization of analytical methods and
- Global harmonization of methods

Overview of template

TEST PRODUCTS?

- Limited definition of test parameters
  - » EU banned pesticides, mycotoxins
- Varying levels of regulations
  - » Nitrite regulated in China and not elsewhere
  - » Hg in baby food incident in China
- Limited harmonized methods, and
  - » Mycotoxins (AOAC/ISO)
- Highly sensitive for legal, regulatory, and public reasons

Overall, testing a finished product is a high risk proposition

Overview of template

TEST INGREDIENTS ✓

- Early detection opportunity
- Potential to remedy the issue prior to manufacturing
- Vendor/manufacturer engagement possibility
- Proactive mitigation of safety risk
- Cost effective testing

Overall, testing ingredients is a low risk proposition

Overview of template

DAIRY INGREDIENTS

- Critical ingredients for infant and adult nutritional products
- Widely traded nutritional ingredients around the world
- Chief sources of proteins in select emerging marke
- Proven safety incidents
  - Melamine/Cyanuric acid, 2008
  - DCD, 2013
- High public visibility

Overview of template

WHAT TO TEST FOR?

Test Everything

Pros

- Low probability of missing a contaminant

Cons

- High cost
- Significant testing for contaminants not likely to be present
- Arbitrary

Test Nothing

Pros

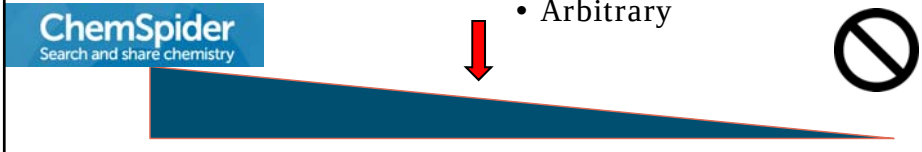
- Low cost

Cons

- High probability of missing contaminants

ChemSpider
Search and share chemistry

- Arbitrary



Overview of template

RISK-BASED CHEMICAL CONTAMINANT PROGRAM

Goal: Objectively identify the chemical contaminants that pose a risk to each ingredient.

Failure Mode and Effects Analysis (FMEA)

- Developed by engineers in the 1950
- Assigns values to two components of risk:
  - Probability – the likelihood that an even will occur
  - Severity – the impact if an event were to occur

The product of probability and severity can then be used as the basis for a program to control chemical contaminants

Overview of template

CREATION OF A RISK-BASED PROCESS

'A risk-based strategy for controlling chemical contaminants as relevant hazards in food ingredients'

- Paul R. Hanlon (Abbott Nutrition), Jason J. Hlywka (Kraft Food Group, Inc.), Joseph A. Scimeca (Cargill, Inc.)

Food Protection Trends, vol. 35, no. 2, pp. 89-100, March 2015
Volume 35, Issue 2, Pages 89 – 100

Salient Features:

- Defines a process for creating a program to control chemical contaminants
- Provides objective criteria through which to determine the risks of specific chemical contaminants (severity and probability)
- Describes examples of how the process can be used

Overview of template

RISK-BASED EVALUATION OF CHEMICAL CONTAMINANTS PROCESS

- Define categories of ingredients

  Grouping similar ingredients to maximize efficiency

- Define chemical contaminants that are in scope

  Based on multiple inputs (regulations, data, emerging issues)

- Define the severity of toxicity of chemical contaminants

  Using defined criteria to group contaminants of similar hazard

- Define the probability of a chemical contaminant being present

  Using defined criteria that evaluate the probability of a contaminant being present in a specific ingredient category

Overview of template

SELECT CONTAMINANTS CATEGORIES

- Pesticides/herbicides
- Veterinary antibiotics/Banned drugs
- Mycotoxins (M1, B1, B2, G1, G2)
- Economic adulterants (Mel/CYA, DCD, others)
- Persistent organic compounds (PCB/PCDD/Dioxins)
- Heavy metals (Pb, Hg, As, Cd)
- Inorganic anions (nitrite, nitrate, thiocyanate, fluoride)

Overview of template

TESTING STRATEGY

- Use of official methods (AOAC/ISO methods)
- Definition of harmonized methods
- Definition of standardized test package for dairy ingredients
- Harmonized test limits, test methods, and testing limits

Overview of template

FINAL OUTCOMES

- An internationally harmonized testing program which enables dairy ingredients safety in a preventative fashion.
- Potential to cut down testing and lower trade barriers.
- Potential to broaden ingredients supply chains without elevating safety risks.
- Shifts focus away from testing finished products.
- Potential to reduce rogue testing of product.
- Improves public confidence in finished products.
- Potential to revolutionize public health in the emerging markets.
- A significant shared value opportunity for nutritional business.

Overview of template

SUMMARY

Safety Drivers

- Global Supply Chain
- Ingredients
- Chemical Contaminants
- Public Safety Concerns
- Regulations

Vision

A risk based approach to ensure the safety and quality of ingredients

Business Outcomes

- Definition of harmonized analytical methods
- Vendors and industry partnership
- Ingredients controls
- Enhance IF safety
- Reduce business risk

ACKNOWLEDGEMENTS

Cross functional teams in

- Analytical R&D
- Regulatory Affairs
- Medical Safety, and
- QA, an d
- Management

BACKUP SLIDES

EU REGULATED PESTICIDES (IF)

ANNEX VIII

PESTICIDES WHICH SHALL NOT BE USED IN AGRICULTURAL PRODUCTION INTENDED FOR THE PRODUCTION OF INFANT FORMULAE AND FOLLOW ON FORMULAE

Table 1

Chemical name of the substance (residue definition)
Disulfoton (sum of disulfoton, disulfoton sulfoxide and disulfoton sulfone expressed as disulfoton)
Fensulfothion (sum of fensulfothion, its oxygen analogue and their sulfones, expressed as fensulfothion)
Fentin, expressed as triphenyltin cation
Haloxyfop (sum of haloxyfop, its salts and esters including conjugates, expressed as haloxyfop)
Heptachlor and trans-heptachlor epoxide, expressed as heptachlor
Hexachlorobenzene
Nitrofen
Omethoate
Terbufos (sum of terbufos, its sulfoxide and sulfone, expressed as terbufos)

Table 2

Chemical name of the substance
Aldrin and dieldrin, expressed as dieldrin
Endrin

EU Commission Directive 2006/141/EC

STAKEHOLDER PANEL ON INFANT FORMULA AND ADULT NUTRITIONALS (SPIFAN)

Jaap Evers, International Dairy Federation (IDF)

Dr. Jaap Evers has 30 years of combined experience in analytical R&D and methodology development, quality assurance, global harmonisation of analytical standards and regulatory advocacy. He started his career in 1984 as a research chemist in an industrial laboratory in the Netherlands and joined the New Zealand dairy sector in 1988 where he had several senior technical, R&D and managerial roles. As from 1 March 2015, he holds two 0.5 FTE roles, i.e. Senior Regulatory Manager – Global Standards in Fonterra's corporate regulatory team, and Global Dairy Sector Leader – Standards for the International Dairy Federation. Both roles focus strongly on international harmonization of standards affecting the global dairy sector.

Global dairy sector strategy - Standards

Jaap Evers

AOAC SPIFAN Stakeholder Panel meeting
17 March 2015

Outline

1. International Dairy Federation (IDF) and Global Dairy Platform (GDP)
2. Standards setting – what, why, how
3. Global drivers and regulatory situation
4. Summary

IDF Facts and Figures

- Founded in 1903
- Over 75% of world milk production
- Membership on country basis
- >1200 experts

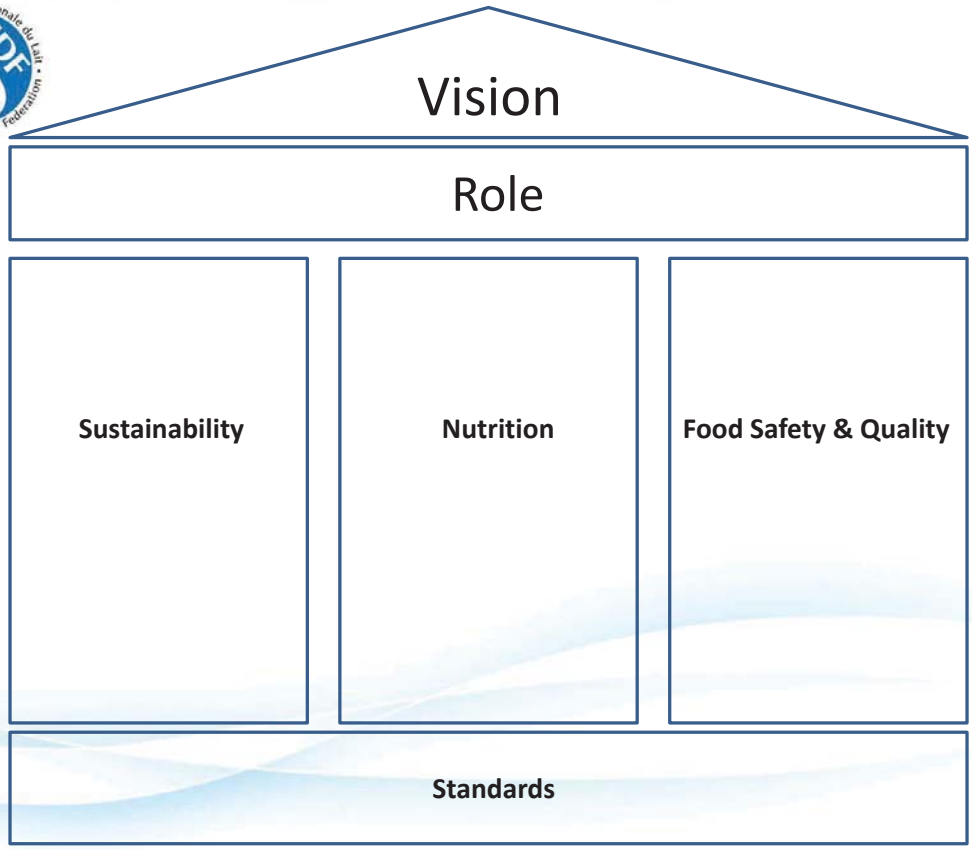
INTERNATIONAL DAIRY FEDERATION

Our role

Provide science-based expertise and consensus for the global sector and be the global voice of dairy to intergovernmental organizations and stakeholders

Work is grouped into 9 areas

Methods of analysis & sampling	Sustainability	Nutrition & Health
Food standards	Environment	Dairy Science & Technology
Food Safety & Hygiene	Animal Health & Farm Management	Dairy Policies, Economics & Marketing



Global Dairy Platform

- Formed in 2006

GLOBAL DAIRY PLATFORM
KNOWLEDGE · INSIGHT · GUIDANCE

- Members: dairy corporations, cooperatives and associations
- Operates in the pre-competitive space

Global Dairy Platform

- Mission: to align and support the dairy industry to promote sustainable dairy nutrition

- Strategic priorities
  - Nutritional Security
  - Sustainability
  - Chain Integrity

Collaboration IDF-GDP

GLOBAL DAIRY PLATFORM
KNOWLEDGE · INSIGHT · GUIDANCE

Amplifies the voice and impact of the dairy sector by:

- Leveraging the respective strengths and cultures of the two organisations

- Ensuring dedicated leadership of priority areas and ongoing strategy development and prioritisation in these areas

- Providing the resources to complete work in a more timely manner, i.e. work is not delayed through a lack of funding

Global Dairy Sector Leaders

• Nutrition	Greg Miller
• Sustainability	Brian Lindsay
• Food Safety & Quality	Nico van Belzen
• Standards	Jaap Evers

Outline

1. IDF and GDP
2. **Standards setting – what, why, how**
3. Global drivers and regulatory situation
4. Summary

What?

Standard =

codified criteria, instructions or recommendations

What?

- Policies
- Laws
- Regulations
- Protocols/Codes of practice
- Procedures
- Food standard specifications
- Guidelines
- Fact sheets

Why?

How? - Global consensus through IDF

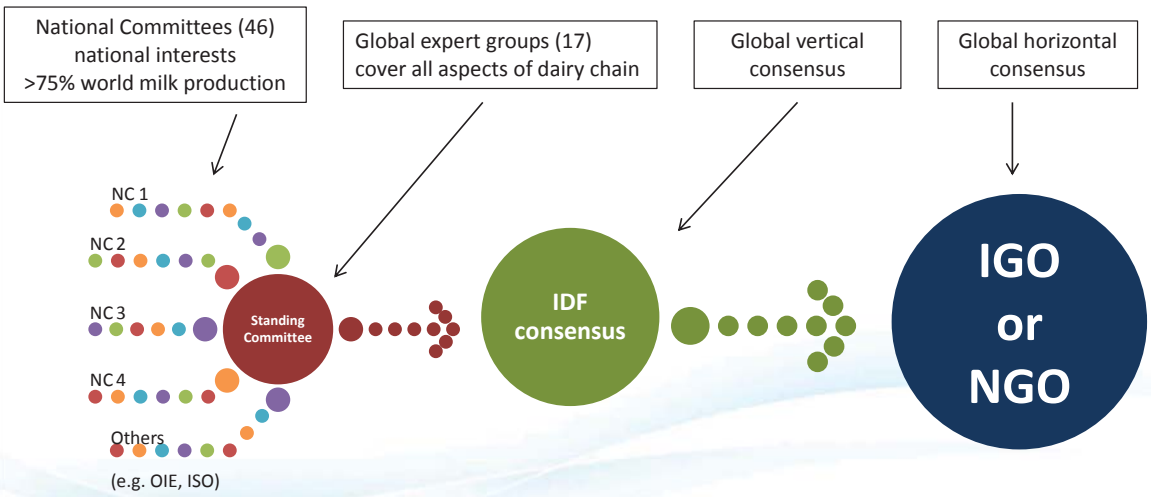
High coverage and broad representation recognized in formal agreements by IGOs

National Committees (46)
national interests
>75% world milk production

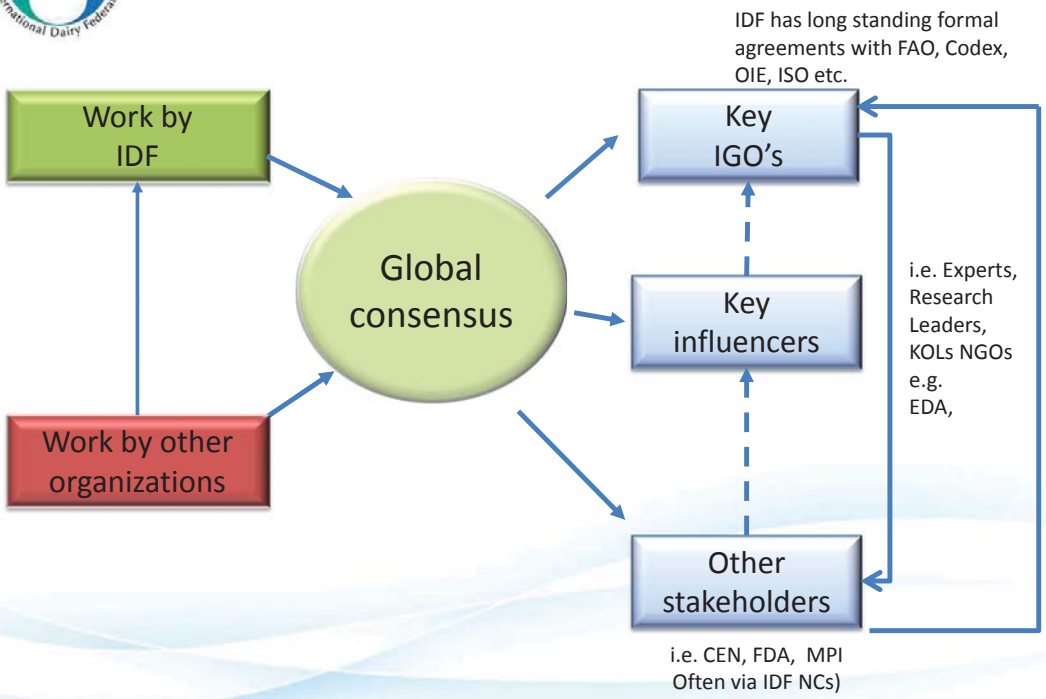
Global expert groups (17)
cover all aspects of dairy chain

Global vertical consensus

Global horizontal consensus



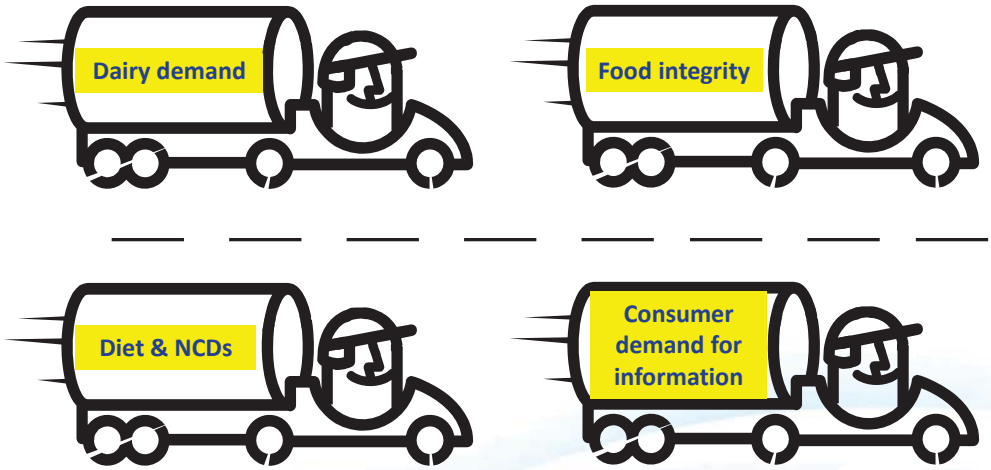
How?



Outline

1. IDF and GDP
2. Standards setting – what, why, how
3. **Global drivers and regulatory situation**
4. Summary

Global drivers for dairy-related standards



Regulatory environment – what it should be

Regulatory environment – reality

"We develop everything: from sub standards to double standards."

Modified with permission from *The Non-profit Center*, La Salle University

Liaisons

Strategic objective: promote *global harmonization* of dairy-related methods of analysis & sampling

Examples IDF/ISO standards

Gross Composition	Minerals & trace elements	Contaminants/ adulteration
Fat	Na, K	Pesticides & PCBs
Protein	Ca, Mg	Melamine & cyanuric acid
Moisture	Fe, Cu, Pb	Milkfat purity
Lactose		Soy & pea proteins
		Aflatoxin M1
		Antimicrobial residues

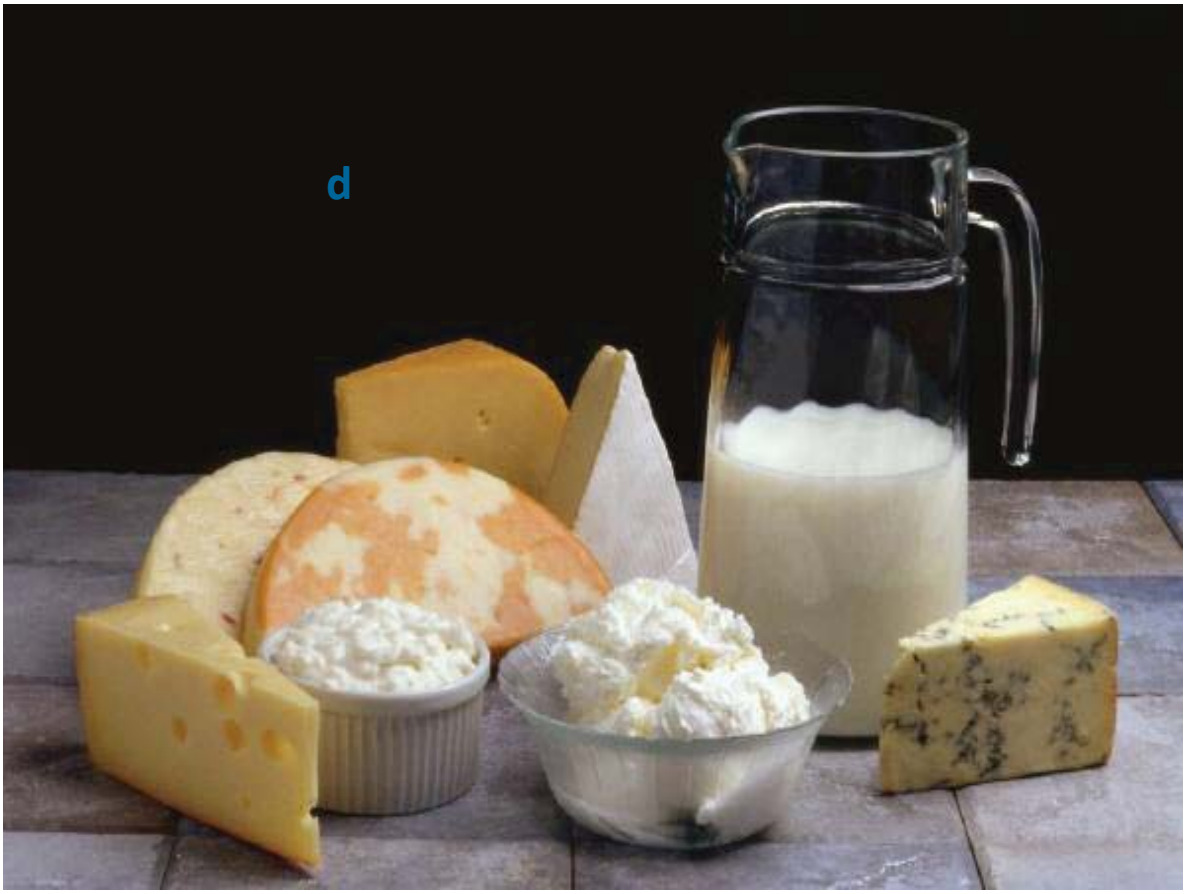
Examples IDF/ISO standards

Microbiological	Physical	Other
Lactobacillus acidophilus	Insolubility index	Nitrogen solubility index
Pseudomonas spp	Dispersibility & wettability	Lactate/s
Salmonella spp	Bulk density	Titratable acidity
E-sakasakii	Heat treatment intensity	Benzoic & sorbic acids
E-coli	White flecks number	Nitrate/nitrite
Thermoresistant spores	Coffee test	Iodide
Bacteriological quality- guidance routine methods		Vitamins A & D

Summary

With coordinated standards strategy we

- Align cross-sector efforts to shape the future global regulatory framework
- Progress global harmonisation and alignment
- Leverage limited resources
- Are collectively better placed to provide nutritional security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STAKEHOLDER PANEL ON INFANT FORMULA AND ADULT NUTRITIONALS (SPIFAN)

Hans Cruijsen, FrieslandCampina Domo

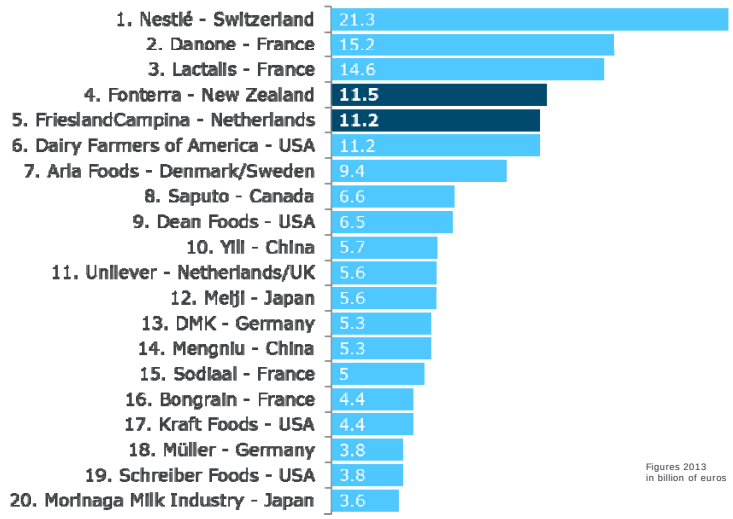
Hans Cruijsen was born in the Netherlands. After completing Secondary school in 1978, he studied higher professional laboratory education with major in analytical chemistry. After graduating in 1982 he studied Food technology at University Wageningen with Minors in microbiology and Toxicology and Major in Dairy technology. After graduating in 1987 he started to work at Danone R&D in Zoetermeer (the Netherlands) and worked in the field of infant food and clinical food. In this period Hans also prepared a PhD thesis on Physical stability of caseinate – stabilized emulsions during heating. He graduated his PhD in 1996. During 1996-2001 Hans worked as development manager cheese and developed and patented in-line measuring techniques for cheese based on NIRS and in line. After moving to the Central laboratory of FrieslandCampina in 2001 he succeeded in accreditation (ISO 17025) of the analytical chemical department in 2002. He built expertise in main components, vitamins, minerals and trace elements, NIRS (in-line technology) contaminants and allergens.

He became member of the Dutch standardization institute on analytical methods for dairy products and on IDF standing committee on analytical methods for composition. In IDF he became project leader on method for minerals and trace elements. He also became member of the Dutch standardization on analytical methods on vitamins and later on member of ISO TC 34 Working group on vitamins and other nutrients. During 2011 and 2012 he worked on introducing GB methods on his laboratory in cooperation with Chinese CAIQ. As stakeholder in SPIFAN-II he participated in several multi lab studies in 2014-2015.

INFANT FORMULA NUTRITIONAL INGREDIENTS PROGRAM

CHALLENGES IN COMPOSITIONAL AND CONTAMINANTS TESTING OF DAIRY INGREDIENTS

Ingredient Companies Perspective



Food quality & safety

- The dairy industry has long established quality and safety standards
- Active participation in internationally recognized standard setting organizations

International Organization for Standardization

3

Our belief: you cannot inspect safety & quality into a product, you have to build it in: 'quality by design'

- A good food safety & quality management system is the best assurance for safe and high quality products
- Product release testing is only one 'step' and sample based (never 100%)
- Quality of dairy products starts at the source

4

FrieslandCampina Foqus program
From Grass to Glass
For Farmers




Milk	Cow	Process	Environment
▪ Milk ▪ Milking ▪ Milk storage ▪ Energy saving	▪ Cow ▪ Housing ▪ Health ▪ Medicines	▪ Feed quality ▪ Water ▪ Sustainable Feed	▪ Clean farm ▪ Grazing ▪ Energy production ▪ Biodiversity ▪ Mineral use

Fonterra farmer shareholders support program

Fonterra farmer shareholders have access to a range of services, including:

Farm Business: This is where farmers manage their dairy business online.

The Food Safety Team: This team works to ensure the delivery of safe, high-quality milk to Fonterra manufacturing sites.

Regional Supplier Services Teams: These teams are on hand to deal with any issues.

Sustainable Dairy Advisors: To help Shareholders comply with Fonterra's environmental requirements and can assist with national and local regulatory compliance.

Fonterra Shareholders' Council: The Council is a national body of Shareholders who represent the interests of the Co-operative.

Sourcing quality milk includes milk transport management

Raw milk quality is assured by systematic inspection before, during and after transport

Cleaning
- Each tank or truck must be clean before transport

Professional milk truck drivers
- Certified to carry out professional inspections
- Regular training and two yearly assessments

Proportional sample
- Collective proportional sample taken to test for a.o. antibiotics
- Final inspection on arrival at production location

Max distance 70k (1.5hr)

Inspection at the farm
- Tank guard inspection (on stirring frequency and temperature)
- Temperature, odor and color check
- Milk sample taken for laboratory analysis

Tracking and tracing
- GPS tracking of samples to ensure accurate retrieval of key particulars of milk supply

Laboratory analysis
- Milk samples analyzed at Qlip
- Payment depends on milk safety and quality
- Results communicated via intranet
- Proven effectiveness

8

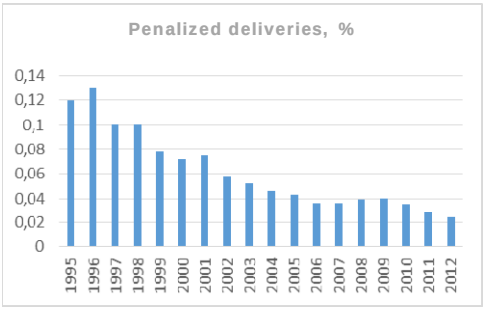
Farmers are rewarded based on the quality and safety of their milk

EXAMPLE

Every milk delivery is tested and farmers are paid according to composition, safety and quality…

Frequency	Parameter
Every delivery	▪ Temperature and color ▪ Fat, protein, lactose, urea ▪ Antibiotics ▪ Free fatty acids ▪ Freezing point ▪ Somatic cell count
2x per month	▪ Bacterial count
1x per month	▪ Butyric acid spores ▪ Sediment
2x per year	▪ Chloroform

… leading to improvement of quality and safety metrics over time



Testing is done by independent laboratory (Qlip) under supervision of government

Quality standards at factory level to maintain good quality product

FrieslandCampina FSSC 22000 based Quality manual, applicable to all manufacturing sites

Version 4.0

Fonterra Safety & Quality Policy

1.0 Intent

1.1 This group policy defines Fonterra's commitment and requirements to food safety and quality.

2.0 Scope

2.1 This policy applies to all Fonterra's global operations as well as joint ventures where Fonterra exercises management control. Where Fonterra does not have management control, the owning Fonterra business unit must ensure the joint venture's policies are consistent with Fonterra's.

TESTING & MONITORING PROGRAMS

Testing programs

Internal testing programs

- Incoming dairy control
- In process testing
- Final product testing

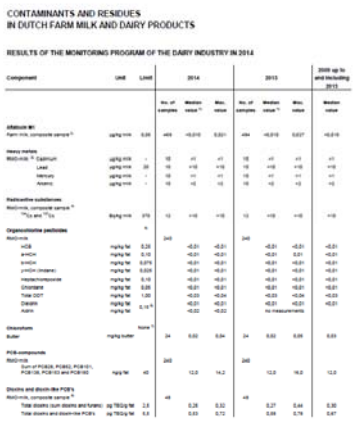
Depending on product & location

External testing programs

- Industry wide monitoring
- Dairy authorities inspection and testing

Industry-wide Monitoring system on contaminants in the Netherlands

- Cross company working group of experts set parameters & frequencies
- Independent laboratory, under government control performes testing
- Monitoring for compliance
  - Aflatoxines
  - Radioactive substances
  - Pesticides
  - PCB's, dioxines, dioxine like PCB's
  - Polyaromatic hydrocarbons
  - Melamine and cyanuric acid
  - Anthelmintics and antibiotics
- Additional survey studies are added based on issue management


CONTAMINANTS AND RESIDUES
IN DUTCH FARM MILK AND DAIRY PRODUCTS

RESULTS OF THE MONITORING PROGRAM OF THE DAIRY INDUSTRY IN 2014

13

Industry-wide Monitoring system in New Zealand

- National chemical contaminants program (NCCP)
- Independent laboratories, under government control performes testing
- Monitoring for compliance
  - Agricultural compouneds and veterinary medicines
  - Radionucletides
  - Environmental contaminants- organochlorines, organophosphates, dioxin and dioxin-like PCBs, mycotoxins
- Additional survey studies are added based on risk based issue management criteria

Ministry for Primary Industries
Manatū Ahu Matua
NEW ZEALAND

14

Conclusions

- Compositional and contaminant control is best managed throughout the supply chain and should not be soleley based on ingredient or end-product testing.
- Professional dairy companies have already programs in place for compositional and contaminant control within the supply chain.
- All systems strongly linked to existing international quality standards.

Questions?

STAKEHOLDER PANEL ON INFANT FORMULA AND ADULT NUTRITIONALS (SPIFAN)

(AOAC/ISO COOPERATIVE)

Erik Konings, Nestlé
SPIFAN Working Group Chair, Folic Acid
Chair, ISO/TC 34/WG 14 – Vitamins, Carotenoids and Other Nutrients

Erik Konings was born in the Netherlands. After completing Secondary school in 1977, he studied higher professional laboratory education with majors in analytical and clinical chemistry. After graduating in 1984, he started his professional career at the then called Food Inspection Service in Maastricht, the Netherlands. During 1989 to 1996 he was involved with the development of analytical methods for the analysis of vitamins in food and food products.

In 1996 he started his PhD study "Dietary folates in human nutrition" in collaboration with the departments of Human Biology and Epidemiology of Maastricht University.

During this study, which he completed in 2001, he obtained a MSc-degree in epidemiology. Since 1998 he was appointed as Senior Scientific Staff Officer at the department Research & Development of the Food and Consumer Product Safety Authority (VWA) in the Netherlands. He was (co)author of more than 30 scientific publications.

In 1997 he became a member of the Methods Committee on Food Nutrition of AOAC International and since 2001 he is convenor of a working group on vitamins & carotenoids of the European Committee for Standardization (CEN). In September 2008 he started at the European Food Safety Authority (EFSA) in Parma, Italy, for a secondment as Scientific Officer at the Data Collection and Exposure Unit and from there accepted, in June 2009, a position as Project Manager at the Quality and Safety Department of Nestlé Research Centre in Lausanne, Switzerland. Per September 2010 he was appointed as Group Manager of the Method Management Group at the Quality and Safety Department of Nestlé Research Centre in Lausanne, Switzerland.

Since 2009 he is member of the International Dairy Federation (IDF), Standing Committee Analytical Methods for Additives and Contaminants, and participates in Codex Committee for Methods of Analysis and Sampling (CCMAS) since 2010.

AOAC-ISO-IDF Collaboration

Erik Konings

March 17, 2015

Submission of SPIFAN methods for endorsement by CODEX

- November 1, 2015, first opportunity to submit SPIFAN AOAC Final Action methods for endorsement by CODEX.
- Advantages of submission as AOAC/ISO/IDF
  - Globally harmonized dispute resolution methods
  - Increases global availability and accessibility

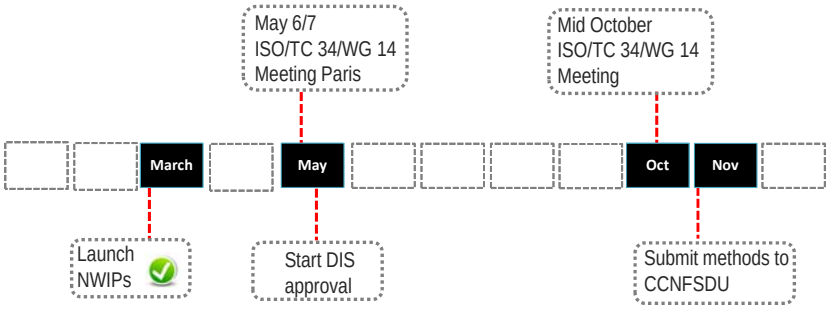
Actions/Timing for endorsement by CODEX

Action	timing
Submission recommended methods for dispute resolution to Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU)	1 November 2015
CCNFSDU requests the Codex Committee on Method of Analysis and Sampling (CCMAS) for endorsement of their recommendations	February 2016
Endorsement of CCMAS recommendations by the CODEX Alimentarius Commission (CAC)	July 2016
Inclusion of methods in Codex Standard 234: Recommended methods of analysis and sampling	

Methods for submission

AOAC OM	Nutrient(s)	ISO committee
2012.10	Vitamin A and E	ISO/TC 34/WG 14
2011.11	Vitamin D	ISO/TC 34/WG 14
2011.10	Vitamin B_{12}	ISO/TC 34/WG 14
2011.20	Nucleotides	ISO/TC 34/WG 14
2011.18	Inositol	ISO/TC 34/WG 14
2012.16	Pantothenic acid	ISO/TC 34/WG 14
2012.22	Vitamin C	ISO/TC 34/WG 14
2011.19	Ultra trace minerals (Cr, Mo, Se)	ISO/TC 34/SC 5
2012.13	Fatty acids	ISO/TC 34/SC 5
2012.15	Iodine	ISO/TC 34/SC 5

2015 timeline WG14 methods



ISO/TC 34/SC 5

Milk & milk products

IDF/ISO Analytical Week

Analytical Week, 13-17 April 2015, Namur, BE

Discussion of NWIPs for iodine and ultra trace minerals.

Summary

- Joint submission of 10 SPIFAN Final Action methods to CCNFSDU by AOAC/ISO/IDF on November 1 2015.
- Endorsement by CCMAS followed by the CODEX Alimentarius Commission foreseen for February and July 2016, respectively.